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INTERNET PHARMACY AND DRUG IMPORTATION: EXPLORING RISKS AND BENEFITS

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING UNITED STATES SENATE

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INTERNET PHARMACY AND IMPORTATION: EXPLORING RISKS AND BENEFITS

WEDNESDAY, JANUARY 26, 2005

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee convened, pursuant to notice, at 10:02 a.m., in room 628, Dirksen Senate Office Building, Hon. Gordon H. Smith (chairman of the committee) presiding.

Present: Senators Smith, Craig, Kohl, Wyden, Nelson, and Clinton.

OPENING STATEMENT OF SENATOR GORDON SMITH, CHAIRMAN

The CHAIRMAN. Good morning. I would like to welcome everyone to the Senate Special Committee on Aging's first hearing for the 109th Congress.

We have an outstanding hearing planned for today with testimony from Surgeon General Richard Carmona—we welcome you, sir—and other witnesses who can speak to the topic of "Internet Pharmacies and Prescription Drug Importation: Exploring the Risks and the Benefits."

At this first hearing, I would like to inform everyone that we will continue with the committee's practice of allowing all members of the committee to make a 5-minute opening statement, if they wish. Following their remarks, we will turn to the Surgeon General for his testimony and then allow everyone to ask their questions. To ensure everyone has an opportunity to ask questions, I will request that on the first round, we limit them to 5 minutes.

The Aging Committee has a storied history. For over four decades, this committee has given voice to millions of Americans over the age of 65 by researching, publicizing, and legislating on issues of importance to them. It has shined a light on unspeakable abuses, brought justice to those who would defraud America's seniors, and helped shape public policy. It has done so in a very bipartisan spirit, a spirit which I eagerly embrace and which I intend to carry forward in this committee.

I am honored to be the 13th chairman of this committee and to have an opportunity to continue to lead in issues of importance to our seniors. For the coming year, I am eager to work with all of my colleagues on this committee from both parties to impact key legislative priorities. I also plan to continue the committee's tradition of performing oversight activities of the appropriate agencies

and will rigorously investigate allegations of wrongdoing against seniors.

The President has challenged the Congress to devote time and resources to reviewing the Social Security program and to determine the best means to ensure its long-term solvency. Over the next 6 months, this committee will be holding a series of hearings focused on this issue, as well. We will be looking at Social Security's long-term solvency and also discussing the larger picture of financial security for retirees. You see, Social Security is one of the important components in a bigger picture that we as a nation must understand if we are to preserve Social Security, maintain its importance as it relates to the broader issue of retirement security.

Along with Social Security, the Medicare program has been a key component to ensuring seniors' independence and health. It delivers access to health care for all. In 2003, as a member of the Senate Finance Committee, I was a part, with my colleagues, of drafting legislation that modernized the Medicare program and added a prescription drug benefit. This benefit alone is the largest enhancement of Medicare in its history. It was an important modernization, and as the Centers for Medicare and Medicaid begin implementation, it is the committee's responsibility to oversee this process and to ensure that the new benefit meets the needs of Medicare's beneficiaries. To do so, the drug program must be simple, easy to navigate, and provide real savings to seniors.

We also must ensure that as we transition the so-called dual eligibles into the Medicare drug program that they receive comparable assistance to the benefit provided by Medicaid. Often, these are the oldest and the poorest and the sickest of our fellow citizens and we must ensure that they are taken care of.

Given that it is the health care safety net for over 50 million people and provides the only coverage for long-term care, the committee will also spend time reviewing the future of the Medicaid program. Many challenges have faced this program over the past few years, and during that time it has become apparent to me that Congress must take an extensive review of that program and chart its course for the next generation. Medicaid has served our country's low-income and disabled populations well. But to ensure that it continue, we must revisit its mandate and determine how to make improvements.

In preparation for reauthorization, we will also review the Older American Act. This Act, which funds seniors' programs under both the Department of Health and Human Services and the Department of Labor is the cornerstone of seniors' service programs. Significant changes were made in 2000 and it is the responsibility of this committee to review those changes, assess their effectiveness, and determine if other enhancements are necessary.

As you can see, this first session of the 109th Congress promises to be exciting and busy. I pledge to do my best as chairman to lead the committee fairly and in a bipartisan fashion. I am especially pleased to have the opportunity to work closely with Senator Herb Kohl of Wisconsin, who is our ranking member. Herb, whatever you want, we are going to make sure your side is accommodated. We have already discussed various panels. We will do more of that

in the future to make sure that both sides get to present their perspective on issues of importance to our seniors.

I want to thank Chairman Craig for his service as chairman of this committee, and his continued interest in these issues is certainly appreciated. I will look forward, Larry, to leaning on you for advice and I thank you in advance.

I especially want to note my colleague, Ron Wyden, whose entire career, if it has a polar star to it, is a concern for seniors, he having been critical in the founding of the Gray Panthers. His presence here this morning is evidence of his commitment to that, so Ron, thank you for being here and your continued interest in this committee.

With that, I will turn the mike to Senator Kohl for his opening statement.

OPENING STATEMENT OF SENATOR HERB KOHL

Senator KOHL. I thank you, Mr. Chairman, and I want to congratulate you on your role as chairman of this committee. You have been a leader on issues that affect our nation's senior citizens. We have worked together in the past and you have always brought a thoughtful, practical approach to your work that will serve you well as you steer this committee. The committee is clearly in good hands and I am most happy to have the opportunity to work with you.

The CHAIRMAN. Thank you.

Senator KOHL. This first hearing is on a topic that is critical for many of our nation's senior citizens. Prescription drugs have become so expensive here in America that many seniors cannot afford to buy the medicines they need. This is a system in dire need of reform.

Today, American taxpayers foot the bill for most all of the research on the drugs we are talking about today. At the same time, Americans are charged the highest prices in the world for those drugs, which are sold in other countries for a fraction of the price.

Faced with the choice of buying the medicines they need to keep them healthy or paying for food and rent, many seniors are turning to Canada and the Internet to find drugs at more reasonable prices. Last August, I met with seniors from Wisconsin who are getting their medicines from Canada. Mary Ellen Hayes from De Pere, WI, told me how she was able to cut her $582 drug bill to $370, and Carol Johnson of Eau Claire saves 30 to 50 percent on most of her prescriptions by going through Canada.

Many States and local communities are doing the same thing. The State of Wisconsin launched a website last February that connects Wisconsin consumers with three approved Canadian pharmacies. So far, the website has already had nearly 1.4 million hits. Today, we will hear from Mary Jorgensen from the Coalition of Wisconsin Aging Groups about their efforts to help their members find low-cost drugs, often through Canadian mail order and Internet pharmacies.

The programs in operation today are based on Canadian and Internet pharmacies that have been inspected and certified to be legitimate, but there are also many unregulated sites in operation today. As long as the Federal Government refuses to put a sound regulatory system in place for drug importation, then we are leav-

ing Americans at risk of falling prey to unscrupulous people who might well try to taint the drug supply.

This is a legitimate safety issue and I believe that we can and must address it. Several bills have already been introduced to create stronger safety standards, but as Congress continues to debate this issue, the reality is that drug importation is already happening, so it is time for the administration to stop defending the status quo, issuing reports and setting up new roadblocks, and start working with Congress to give Americans the price relief and safety assurances they need and deserve.

Again, I want to thank you, Mr. Chairman, for holding this hearing. I know we share some of the same views on this topic and I look forward to working with you to move this important issue forward.

The CHAIRMAN. Thank you, Senator Kohl.

Senator Craig.

OPENING STATEMENT OF SENATOR LARRY CRAIG

Senator CRAIG. Mr. Chairman, thank you. Let me say at the outset of my comments that I appreciate those kind words that you have just offered on my behalf. I leave the chairmanship of this committee with some concern, not that it is in good hands, I know that, but because I tremendously enjoyed my tenure here. I spent many hours behind that microphone, chairing hearings of the nature that you are continuing. You are so right. This is a forum that speaks on behalf of America's seniors. It can be very probative. It can be illustrative. Most importantly, it can build a record for all of us here in the Senate.

Your dual service on Finance is so important because much of what we ultimately do ends up in Finance, and yet Finance, because of its workload, oftentimes doesn't hold the kind of hearings that should be held, that can be held, that we have held and that you are going to hold at this committee, so thank you.

I come today not to hand you the gavel, because I know you will handle it well, but to support you in that effort and to continue my work on behalf of seniors. As you know, this year, in October, is the White House Conference on Aging. I am continuing to chair the Subcommittee on Economic Security for Seniors and want to work very closely with you and this committee to make sure that the voices are effectively amplified at that forum. It is a forum that occurs every 10 years. It is a very important one.

When people think, gee, what does something like a White House Conference do, it came up with an idea called Medicare. It came up with an idea that was the basic product for the Older Americans Act. It really has been a most effective gathering of America's seniors to put forth concepts and ideas that have ultimately resulted in public policy. So let us stay close and work on that issue.

What we are about today and the hearing that you have assembled and the witnesses that you have in front of us are critically important, from the Surgeon General who is before us to many others who will speak to us.

I must tell you that in my new life as chairman of the Veterans' Affairs Committee that this past week, I visited a pharmacy at a veterans' hospital in Spokane, WA. The line was long, but fast, and

it was interesting to me that a very small pharmacy was handling a large volume of people. I asked, how is that being done? Here is how it is being done, and quite effectively and with great efficiency.

There are six regional robotic centers of large warehouses of pharmaceuticals, prescription drugs that the government buys in volume effectively. So if I am standing at the pharmacy window of a veterans' facility, I may get a two- or three-day supply, but in my mail will arrive the balance in 24 hours, filled by a machine with a 99.9 percent accuracy at one of these regional centers, the Spokane Center, the Spokane Hospital and Spokane patient being served by a very effective center in California that serves regionally.

I am going to be visiting those. It is certainly an approach that the Veterans' Administration has proved very efficient and serves its clientele well. Always, the question is access, and there it is not so much the cost as it is actually gaining access to the system because of the ultimate costs involved.

So what we do here is important. Pharmaceuticals, prescription drugs are the new medicine of this century, the new health care of this century. We know that. For all of us who are seniors-in-waiting, this committee's role is certainly important for our future. For those of us who think we are seniors-in-waiting, I am quite confident we have already been found by the AARP, so I guess we are now one.

But thank you again for being willing to accept the leadership of this committee. I ask unanimous consent that my full statement become a part of the record and I look forward to working with you on the continuation of all of these valuable issues that you are pursuing, that we have pursued, and I know that this committee will want to continue doing into the future. Thank you.

The CHAIRMAN. Without objection, your statement will be included in the record.

The CHAIRMAN. Senator Wyden.

OPENING STATEMENT OF SENATOR RON WYDEN

Senator WYDEN. Thank you, Mr. Chairman. I just want to say it is a thrill to see you, a personal friend and an Oregonian, with the gavel in your hand. Back when I was director of the Gray Panthers, as you noted, we couldn't even contemplate the day when an Oregonian would have this kind of clout on issues important to seniors, so we are really thrilled that this day has come about.

The CHAIRMAN. Thank you, Ron.

Senator WYDEN. Mr. Chairman and colleagues, I think Senator Smith has chosen an important topic because in my view, current Federal policies for regulating Internet pharmacies and prescription drug imports virtually ensure that many vulnerable elderly people get ripped off today. Specifically, I believe that because the policies for overseeing Internet sales do not have the muscle to ensure that our country stays in front of the rip-off artists who constantly get more inventive in trying to come up with ideas to exploit the elderly.

Second, our policy with respect to the importation of pharmaceuticals that can be certified as safe has become so frustrating that many, particularly our States, have gone off on their own to

try to address this issue. It seems to me, our inability to come up with a coherent national policy again ensures that many older people aren't given the opportunity to purchase medicines that are affordable.

The other reason that this is such an important hearing is the Wall Street Journal reported yesterday that just in the last few weeks, pharmaceuticals have spiked again very significantly. They report, for example, Lipitor, the very popular cholesterol drug, just in the last few weeks has gone up about 5 percent. They note that of the 50 biggest selling medicines 31 had price increases since November.

So I think this question of how we look at the matter of containing pharmaceutical prices is important. Senator Smith always works in a bipartisan way, and I think he knows that is my interest. Toward that end, Senator Snowe and I will be introducing legislation next week so that Medicare would be in a position to start using the kind of cost containment tools that the private sector uses in our country to hold down the cost of medicine.

It is incredible that everybody in the United States who purchases medicine in the private sector, when they purchase a significant volume and then they look at buying more, they ask, what kind of a discount will you give me? What can I get when I negotiate with you? The Medicare program is, as far as I can tell, one of the few, if not the only, program that isn't using marketplace forces, isn't using what is available in the private sector to hold down the cost of medicine. Senator Snowe and I will be going after that in a bipartisan way next week.

Mr. Chairman, again, I look forward to many of these kinds of sessions and particularly the opportunity to work in a bipartisan fashion on issues that are so important to millions of seniors and their families.

The CHAIRMAN. Thank you, Ron.

We are joined by the Senator from Florida, Senator Nelson, for your opening statement.

OPENING STATEMENT OF SENATOR BILL NELSON

Senator NELSON. Thank you, Mr. Chairman. Mr. Chairman, each of us are vitally concerned because of our own States. As you all know, I have the privilege of representing a State that has a greater percentage of the population that is elderly, and as a result, this discussion that we will have today is of enormous consequence to our State.

Now, we have gone through all of the trauma of having storefront pharmacies that are either by mail order or telephone, now Internet. They have been closed down. Senior citizens, I am sad to say, in the year 2005 in my State, some of our senior citizens are still having to choose between food or their prescription medicines and that just simply should not be in America in the year 2005.

Indeed, we have had a situation where people have ordered drugs by the Internet or by telephone and all of those packages have been confiscated, confiscated by Customs, not just the particular senior citizen ordering it at that moment, but a whole load of these prescriptions as an attempt to crack down. So what you are hitting here today specifically with regard to the Internet por-

tends a discussion of a whole wider range of issues and that is how do we prevent disruption of getting available and affordable prescriptions to seniors whose lives and quality of life those prescriptions are absolutely necessary.

So I am looking forward to it, Mr. Chairman. It is a pleasure as a new member of this committee to be a part of it.

The CHAIRMAN. Thank you very much, Senator.

Obviously, you are all here to talk about reimportation. I think it goes without saying, while it is illegal, importation is happening and it is happening on a very large scale. It does seem to me that if we can import cars and other farm products and even regulate beef from Canada that of late has had some concern, we have to find a regimen for allowing this to happen legally.

Last year, to that end, Senator Judd Gregg and I introduced a bill called the Safe Import Act, which would have both regulated Internet pharmacies and legalized importation. We are reintroducing that bill today because we continue to believe that importation should be legalized. However, this bill is just a marker. We are reaching out to colleagues on both sides of the aisle to fine-tune the policy and plan to reintroduce a new version in March.

Since 1990, the amount of money American consumers spend on prescription drugs has quadrupled to over $160 billion. At the same time, the growth in importation has exploded. According to IMS Health, U.S.-Canadian cross-border sales of drugs totaled $695 million in 2003. Of this spending, almost two-thirds was done via the Internet. So I guess they didn't catch it all, Senator Nelson. But this is what is happening.

I decided to call this hearing today to look into the relationship between Internet pharmacies and importation. I know that many of the Internet pharmacies are unsafe. There are some unsafe ones. But clearly, there are some very safe ones.

I have read the report and spoken with the FDA experts. However, I continue to feel that we have become so focused on debating whether importation should be legalized that we have lost track of the reality that importation happens.

So at today's hearing, we are privileged to have as our first witness the Surgeon General of the United States, Richard Carmona. We thank you, General, for your presence here. I promised you that we would go easy on you, but clearly, there are some strong feelings in the room. But given your diverse experience in health, I am certain you will add a very valuable perspective to our discussions. Welcome, sir, and thank you.

STATEMENT OF RICHARD H. CARMONA, M.D., M.P.H., F.A.C.S, SURGEON GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. CARMONA. Thank you, Mr. Chairman. Good morning. Mr. Chairman, distinguished members of the committee, thank you for asking me to join you today. My name is Richard Carmona and I am the United States Surgeon General.

I was also the Chairman of the HHS Task Force on Drug Importation, which was comprised of 13 senior executives with diverse experience from across the Federal Government. Secretary Thompson created the task force in February 2004 to advise him on the questions posed by Congress in the Medicare Modernization Act about the safety issues surrounding the importation of prescription drugs.

As you know, the role of the Surgeon General is to protect and promote the health and well-being of the American people. Everything I do as Surgeon General is based in science and that was my guiding principle in leading this task force. We went there where the facts and the science led us. In doing so, we also ensured an open and transparent process.

The task force held six listening sessions, heard from more than 100 presenters, and received information from over 100 individuals and organizations via an online docket.

In addition, I led a site visit to the John F. Kennedy International Airport in New York City to see how imported drugs are processed by the United States Customs and Border Protection and by officials of the Food and Drug Administration. This visit demonstrated to us the huge challenge of ensuring the safety of imported drugs.

The report has eight key findings and they are: Our current system of drug regulation has been very effective in protecting the public safety, but it is facing new threats and new challenges. Any change to our current regulatory system must be done with great care to ensure the continued safety and efficacy of our nation's drug supply.

There are significant risks associated with the current illegal importation of drugs for personal use. To just name a few, there are 355 points of entry for access into the United States. This includes 14 international mail branches, 29 express consignment facilities, and 312 ports. FDA inspectors are already stretched thin reviewing the millions of prescription drug packages that currently pass through these points of entry each year.

We all know that illegally purchasing prescription drugs over the Internet without a prescription is relatively easy to do. The reality is that this lack of a relationship between the doctor and the patient is extremely dangerous and potentially fatal. Although some licensed Internet pharmacies provide a legitimate way for people to buy medicines, many Internet pharmacies are not licensed. They are rogue operations. They pretend to be legitimate and are actually providing dangerous products. Now, by dangerous, I mean these drugs are often grossly mislabeled, expired, sub-potent, super-potent, or placebos, and have usually been transported improperly with a complete disregard for safety precautions.

The task force found that it would be extraordinarily difficult and costly for personal importation to be implemented in a way that would ensure the safety and effectiveness of all prescription drugs.

Looking at commercial prescription drug importation, the overall national savings would likely be small. Building the infrastructure to support commercial importation would cost a tremendous amount of money and require significant changes in the law. Consequently, the savings to consumers would be less than one percent of total spending, while intermediaries would probably capture any other savings.

The public expectation that imported drugs are less expensive than American drugs is generally not true. For example, the prices of generic drugs in other countries are, on average, 50 percent more than the prices that Americans pay for the same generic drugs.

Legalized importation most likely would reduce the future development of new drugs for American consumers. It is no secret that pharmaceutical research and development spending would drop. This would result in fewer new drugs at a high cost to Americans' health and well-being.

The effect of importation on intellectual property rights are also likely to be significant.

Finally, the task force concluded that importation raises new liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

In closing, I want to state to you that, like you, I truly appreciate the critical role of prescription drugs in our public health system. Science has brought us medications that can reduce the risk of heart attack and stroke, lower blood pressure, cure infection, and save and enhance life. We must find more ways to provide these life-saving medicines to those who need them. This is being addressed through the Medicare Modernization Act and the new Medicare Drug Discount Card. Today, millions more seniors have access to the drugs they need, and when the Medicare Modernization Act is fully implemented less than a year from now, even more seniors will have even more access to benefits through this new law.

We are also seeing pharmaceutical companies working with the government to ensure greater access to medications. For example, the Prescription Access Card allows uninsured Americans to save money on more than 275 brand-name prescription medicines with even greater savings on generic drugs. On the average, card holders will save between 25 and 40 percent on their prescriptions.

In addition to the new drug discount cards, there are other ways for consumers to save money on prescription drugs. Over the past few years, the FDA has worked hard to speed generic drug approval and availability and consumers are encouraged to comparison shop and to ask their doctor or pharmacist for prescription generic alternatives when possible.

Mr. Chairman, this concludes my oral statement. I would ask that you accept my full written statement for the record. Thank you for the opportunity to be here with you and I would be happy to answer any questions.

The CHAIRMAN. Thank you, General. We will include your full statement, if there is no objection.

[The prepared statement of Dr. Carmona follows:]

Testimony
Before the Special Committee on Aging
United States Senate

Report of the HHS Task Force on Drug Importation

Statement of

Richard H. Carmona, M.D., M.P.H., F.A.C.S.

Surgeon General,
U.S. Public Health Service
Department of Health and Human Services

For Release on Delivery
Expected at 10:00AM
Wednesday, January 26, 2005

Introduction

Good morning Mr. Chairman and distinguished members of the Committee. My name is Dr. Richard Carmona, and I am the Surgeon General of the United States Public Health Service. I appreciate having this opportunity to discuss the work of the HHS Task Force on Drug Importation and issues relating to the importation of prescription drugs into the United States.

Brief Overview of Drug Importation

The Federal Food, Drug, and Cosmetic (FD&C) Act limits the types of drugs that may be imported into the U.S. Currently, the only types of legally imported drugs are: 1) those that are manufactured in foreign FDA-inspected facilities and the subject of an FDA-approved drug application, or 2) those that are U.S.-approved and manufactured in the U.S., sent abroad, then re-imported to the U.S. by the manufacturer under proper controls and in compliance with FD&C Act requirements.

All imported drugs are required to meet the same standards as domestic drugs, and thus cannot be unapproved, misbranded, or adulterated. The FD&C Act prohibits individuals from importing unapproved, misbranded, or adulterated drugs into the U.S. This prohibition extends to drugs that are foreign versions of U.S.-approved medications, and drugs dispensed without a prescription.

Although importing unapproved prescription drugs is illegal, FDA may exercise its enforcement discretion and not take action against illegal personal importation in certain situations. FDA has developed a policy to guide its exercise of enforcement discretion with respect to importation of the products it regulates. This policy is called the personal importation policy, and it was last updated in 1988 in response to concerns that certain AIDS treatments were not available in the U.S. Under the policy, FDA exercises its enforcement discretion under certain circumstances and does not stop individuals with serious conditions from bringing into the U.S. treatments that are legally available in foreign countries but are not approved in the U.S.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)

In 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Medicare Modernization Act or MMA), which provides an important new prescription drug benefit for seniors. MMA also includes provisions aimed at providing lower cost drugs to consumers.

MMA provides authority for pharmacists and wholesalers to import certain drugs from Canada, subject to certain conditions. The drug importation provisions in MMA only become effective if the Secretary of HHS first certifies that

implementing the program will pose no additional risk to public health and safety and will result in a significant reduction in the cost of such drugs to the American consumer. In addition, MMA directs the Secretary of HHS to grant waivers to permit importation of a 90-day supply of any FDA-approved prescription drug imported from Canada from a licensed pharmacy for personal use.

MMA also required the Secretary of HHS to complete a comprehensive study that identifies problems with implementation of existing law and examines a range of issues associated with the importation of drugs.

HHS Task Force on Drug Importation

On February 26, 2004, HHS Secretary Tommy G. Thompson announced the creation of a task force to advise him on how to address the drug importation questions posed by Congress in the Medicare Modernization Act. I served as the chairman of the task force, which was comprised of thirteen senior executives with diverse experience from across the Federal government.

The Task Force was charged with gathering input, ideas, and expertise from the public on issues related to drug importation. One of the main goals of the Task Force was to ensure an open and transparent process that provided an opportunity for all views to be heard. To that end, the Task Force held six listening sessions, including an open public meeting, heard from more than 100 presenters and received information from over 100 individuals and organizations via the Task Force's online docket.

Among the presenters were consumer representatives, pharmaceutical industry representatives, international regulatory and industry representatives, academicians, health care purchasers, professional medical groups, government and elected officials, and members of the public.

In addition, a group of Task Force members conducted a site visit to John F. Kennedy International Airport in New York City to see how imported drugs are processed daily by U.S. Customs and Border Protection (CBP) and Food and Drug Administration (FDA) officials. This site visit demonstrated to us the huge challenge of ensuring the safety of imported drugs.

Report on Prescription Drug Importation

The Task Force produced a report that contains our findings based on all of the information presented to us and expert views solicited from appropriate government agencies. The report is available online at http://www.hhs.gov/importtaskforce/. The key findings of the Task Force are:

1. The current system of drug regulation in the U.S. has been very effective in protecting public safety, but is facing new threats. It should be modified

only with great care to ensure continued high standards of safety and effectiveness for the U.S. drug supply.

- Safety and protection of the public health are paramount; safety should not be sacrificed for affordability.

- There are particular products of concern, including controlled substances, intravenous products, biologics, drugs that must be refrigerated or frozen, drugs that have specific post-marketing risk management programs, drugs that are highly susceptible to counterfeiting on the global market, and those that have less expensive alternatives (i.e., generics) in the U.S., that pose special concerns in the importation context.

- To maintain current levels of safety, standards of practice at the level that currently exist in the U.S. would need to apply to all foreign drug suppliers under a commercial importation program. In addition, Memoranda of Understanding (MOU) may be needed with the affected countries to ensure effective enforcement.

- There are promising new and emerging anti-counterfeiting technologies; however, until they are universally adopted, they cannot be adequately relied upon to secure the safety, efficacy, and integrity of the global market to safely import prescription drugs into the U.S.

2. There are significant risks associated with the way individuals are currently importing drugs that violate the FD&C Act.

    - According to CBP, there are 355 "points of entry" for access into the U.S. This includes 14 international mail branches, 29 express consignment facilities, and 312 ports. Given the broad responsibilities assigned to FDA, only a limited number of FDA inspectors are available to staff the 14 international mail facilities in the U.S. that receive millions of small packages a year, where they historically have had to inspect only a small number of large commercial pharmaceutical imports.

    - FDA currently does not have sufficient resources to ensure adequate inspection of current levels of personal shipments of prescription drugs entering the U.S. Moreover, to maintain an adequate inspection of current levels of commercially imported pharmaceutical products would require significant investment in information technology and personnel, among other things.

- Imported drugs are arriving from all corners of the world, including developed and emerging countries. Nearly five million shipments, comprising about 12 million prescription drug products with a value of approximately $700 million, entered the U.S. from Canada alone in 2003. The report estimates that an equivalent amount of prescription drugs may come in from the rest of the world.

- Many state-licensed internet pharmacies provide a legitimate means for consumers to access safe and effective medicines, but others raise significant safety concerns. Some sellers of imported drugs are "rogue" internet pharmacies that pretend to be legitimate and operate behind facades. Many of the drugs sold over the internet claim to be interchangeable with the approved U.S. drug, but are not.

- Purchasing prescription drugs over the internet without a prescription has been found to be relatively easy to accomplish. In those cases, the lack of an adequate health professional/patient relationship is of particular concern.

3. It would be extraordinarily difficult and costly for "personal" importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs.

    - There is no realistic level of resources that could ensure that personally imported drugs are adequately inspected to assure their safety since visual inspection, testing, and oversight of all personally imported prescription drugs are not feasible or practical at this time.

    - The report estimates that ten million packages containing prescription drugs entered the U.S. in 2003. It is estimated that it would cost $3 billion to examine all of these packages.

4. Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities.

    - A commercial importation program could be feasible but would require new legal authorities, substantial additional resources, and significant restrictions on the type of drugs that could be imported, which could increase the costs of imported drugs.

- Total savings to drug buyers from legalized commercial importation would be one to two percent of total drug spending and much less than international price comparisons might suggest. The savings going directly to individuals would be less than one percent of total spending. Most of the savings would likely go to third party payers, such as insurance companies and HMOs.

- Under legalized importation, intermediaries may capture a large part of the potential savings.

5. The public expectation that most imported drugs are less expensive than American drugs is not generally true.

    - The prices foreigners pay for generic drugs are on average 50 percent greater than prices Americans pay for generic drugs.

    - There is evidence that greater use of U.S.-approved generic drugs by Americans could reduce drug spending by billions of dollars annually.

    - Foreign drug supplies in many countries that might export to the U.S. are sufficiently small relative to U.S. drug consumption as to raise questions about the sustainability of high-volume exports from those countries.

    - To the extent that prescription drugs are eligible for importation from the same company at a lower price than in the U.S., potential quantity constraints imposed by manufacturers or foreign governments would limit the eligible supply and the benefits to U.S. consumers.

6. Legalized importation will likely adversely affect the future development of new drugs for American consumers.

    - Americans have a greater choice of newly launched pharmaceutical products than foreigners. In recent years, more than 40 percent of new drugs were launched first in the U.S.

    - Under a legalized commercial importation program, R&D spending would drop, which could result in between four to eighteen fewer new drugs introduced per decade, at a substantial cost to society.

    - Estimates of reduced benefits, due to reduced R&D spending, to future drug consumers may range from $5 billion to $20 billion per decade without including gains from having a greater variety of

generics in the future. Reduced benefits may significantly offset savings from legalized importation.

7. The effects of legalized importation on intellectual property rights are uncertain but likely to be significant.

    - Importation could impact the intellectual property rights of developers of pharmaceutical products and could be subject to challenge under domestic law, including possibly the U.S. Constitution, and international intellectual property rules.

    - It is likely that intellectual property rights holders will exercise their rights to the fullest extent available under the law and the effects may impact the availability of imported drugs.

    - International agreements recognizing intellectual property rights may be affected by the legalization of importation.

8. Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

    - Allowing prescription drug importation would have uncertain effects on the litigation exposure of manufacturers, distributors, doctors, and pharmacists.

    - To deal with these risks, entities in the pharmaceutical distribution chain would likely take additional costly defensive actions.

    - Some potentially liable parties could be unavailable to U.S. courts and, therefore, to consumers, industry, or health care providers.

Conclusion

As a trauma surgeon, the former CEO of a health system, and now doctor to the American people, I understand the critical role that prescription drugs have in our public health system. It is truly wonderful that science has brought us medications that can reduce the risk of heart attack and stroke, lower blood pressure, cure infection, and save and enhance life. As a society we must find more ways to provide these life-saving medicines to those who need them.

President Bush and Secretary Thompson, as well as my task force colleague Dr. McClellan, have already made great strides with the initial implementation of the Medicare Modernization Act and the new Medicare drug discount card. Today, millions more seniors are getting access to the drugs that they need, and as the Medicare Modernization Act becomes fully implemented in the coming years,

even more seniors will have even more access to the preventative and drug benefits provided through the new law.

In addition to the new Medicare drug discount card, there are other ways for U.S. consumers to save money on domestic prescription drugs. Consumers are encouraged to shop around for price comparisons, ask their doctor or pharmacist for generic alternatives, and take advantage of prescription drug discount cards.

Thank you. I will be happy to answer any questions you may have.

The CHAIRMAN. You talk about many of the drugs that are being imported as unsafe, that they are placebos, that they are sub or super potent. What percentage would you think? I mean, clearly, a lot of drugs are being imported that are safe. Do you have a sense of that?

Dr. CARMONA. Mr. Chairman, we asked those questions, but since we don't know the universe, it is very difficult to tell. What I can tell you, which is exemplified in some of the handouts that we provided you, when we visited the JFK mail facility, there was literally a warehouse full of packages from all over the world, from developing countries, from industrialized nations, many of them packaged in very unsafe ways, and if you look through any of those handouts, you will see sub-potent, super-potent drugs, knock-offs, blatant copies of what we have here in America but really not containing what was purported to be contained.

So I can't give you an absolute number, but based on the volume we saw in that warehouse, which the Federal investigators told us represented only a very small amount because that is all they had the resources to deal with now, it was really very concerning to us.

The CHAIRMAN. Given that importation is happening, if the U.S. Government set about, irrespective of the cost, and we have to consider that, obviously, but say that were not the obstacle, what would be the impact upon the national purchasing agencies of Canada and Europe if all of a sudden America started getting a tremendous amount of its drugs from these countries? Wouldn't it have a downward pressure on the price of our drugs?

Dr. CARMONA. Well, sir, not being an economist, having some general knowledge of the area, that is why in our hearings we brought in economists, some who specialize in this area, some from overseas asking about the issues of the global impact as well as some on the United States. Generally, what they told us was what we end up doing is reimporting or importing price controls and that there were consequences of that. Yes, to the individual, there may be an appreciated discount on one medication or another. But in aggregate, as a matter of policy as to what are the intended and unintended consequences of that policy, they would be significant and may, in fact, eventually erode our robust research and development as it relates to innovation and new drugs, more people less likely to invest in that. It really changes the dynamics of an open market and creates one of a fixed market or one that is being controlled, as other countries do.

So there were some very complicated and difficult issues that we asked truly world experts about to give us input on this issue. So as is stated in the report, if Congress thinks about this and they decide that they want to embark on some form of importation, what we wanted to make sure in the report is that you have all the scientific information to do that risk-benefit, cost-benefit analysis.

The CHAIRMAN. This is purely anecdotal, but in the five town halls Ron Wyden and I did together around the State of Oregon, the comments you hear from seniors, and I am not here to tell the pharmacy companies how to run their business, but they readily say, "You know, if pharmaceutical profits are just for research," fine. But if they are just for advertising Levitra, then they are not

interested. A lot of people are, frankly, quite irritated by the amount of advertising that goes on. That is their business decision, but there is a lot of money that goes into advertising prescription drugs that, frankly, many seniors do not like and would rather that companies reduce their prices. But they have to run their business.

But it seems to me your task force found that legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities. Yet liability, to me, is not a reason to ban it. It is a reason to work on safety.

Dr. CARMONA. Yes.

The CHAIRMAN. So the lack of liability or the prospect of liability to me means that there needs to be more attention. Right now, there is a big dispute in agriculture on beef from Canada. If we can import beef and do it safely, if this issue is of this kind of focus and concern to seniors, it seems to me we ought to be able to come up with some kind of Federal safety standard, not a State standard but a Federal standard to allow this to be done safely.

I, for one, having been in the commodity business myself, I think importation would put tremendous pressure on these other countries, not that it would import price controls to us, but it frankly would change the behavior of some of these countries. It wouldn't if you just did one country, but if you included Europe in the market basket of what is available to seniors, it would have a tremendous market force to the benefit of seniors in this country without necessarily sacrificing research and development, which I think seniors do value.

Do you have a comment on that?

Dr. CARMONA. Yes, sir. Well, I appreciate your comments and generally am in agreement with them, as was our task force. The information we presented, including liability concerns, was not meant to preclude or suggest that importation could not be done, but simply to allow Congress to consider that during their deliberations, that there may be liability implications as well as economic implications, both globally and within the United States.

The CHAIRMAN. Without a standard, liability is very elusive. It seems to me if we had a safety standard or some way to regulate it, liability would be able to be pinned more readily on some of these rogue actors.

My time is up. If there is no objection, we will go back and forth, so Senator Wyden?

Senator WYDEN. Doctor, thank you, and let me start by seeing if I can give a fairly simple example. I find it compelling with respect to the case for importation from Canada, because in Canada, they have a lengthy review process for their pharmaceuticals and many on-line pharmacies there can get certified. They have an actual program for it.

What would be wrong, then, with having a U.S. policy that would allow for U.S. citizens to be directed to those on-line pharmacies?

Dr. CARMONA. Senator, from our standpoint, it is not a right or wrong issue. We were looking at the science to provide information to you. From our perspective, we have stated that commercial importation could be a viable option. We wanted to make sure that you all in your deliberations had all of the information as you move forward to decide it.

Senator WYDEN. Would you support that policy, you personally? I think what is so striking about this is, and again, it comes back to the town meetings that Senator Smith and I have had, and I have had this in other sessions with other colleagues because this is the area I have tried to specialize in. It seems like every time we bring this issue up, those of us who have worked in a bipartisan way—I was one of those Democrats who voted for the prescription drug bill. I have got the welts on my back to show for it. [Laughter.]

Every time we work with the administration on this issue, the goal posts keep moving and we just never seem to have an opportunity to get it across.

So would you be supportive personally of a policy related to Canada, that when the drugs went through a lengthy review process and a pharmacy was certified, it ought to be possible to direct our citizens to those on-line pharmacies should that be U.S. policy?

Dr. CARMONA. Let me say, Senator, that as it relates to any specific policy, before I commit, I would certainly have to look at it.

Second of all, the goal posts for us are pretty fixed. They are all stated in this report quite emphatically based on the questions that Congress posed and we answered those. My job as Surgeon General is to ensure the health and safety of the citizens of the United States, as I know all of you are working in that direction, also. So any policy that you look at that you would like to move forward, the magnifying glass I will hold to it is, is it safe? Can we certify this policy that every American will be guaranteed safe medications? In that case, if that is your will, I would be happy to support such a policy.

Senator WYDEN. Why don't we do it this way. I would like you, if you would, within 30 days, to get back to me and tell me what, if any, problems you see with respect to the proposal I have made. I have given you a concrete example as it relates to an area where I think there is lengthy documentation attesting to the safety, that could work and could provide a tangible opportunity to address this issue. If you would, within the next 30 days, simply tell me what, if any, problems you see with that and——

Dr. CARMONA. Yes, sir, I would be happy to.

Senator WYDEN. Very good. The second area that I want to talk to you about is rip-off artists with respect to Internet sales of pharmaceuticals and other products to seniors. Who at the Federal level is responsible for being the watchdog against these rip-off sales in the health care area? I think one of the reasons we have problems and that the bad guys always seem to be out in front is I can't find who is responsible for making sure that the Internet is not a safe haven for rip-off artists. In your view, who is responsible?

Dr. CARMONA. As it relates to the——

Senator WYDEN. Health care.

Dr. CARMONA. Well, I am saying, as it relates to the health care of the public and the commerce involving drugs and devices, it would be our Federal Drug Administration who is looking at that. But I think one of the problems—you have hit the nail on the head, that there are many that take advantage of the Internet. We have found hundreds of websites that purport to be Canadian websites, some with a stamp of approval saying, "sanctioned by the FDA,"

who really are nothing more than somebody in a foreign country placing that in Canada, drugs being shipped from another country, billings going to someplace in the Caribbean, and so people do take advantage of it.

I agree with you. I think there are multiple jurisdictions there because if you were marketing a product that was not, say, a pharmaceutical, the FDA would have no responsibility. I think then it becomes a trade issue and there are a lot of people who are stakeholders in that endeavor.

Senator WYDEN. Do you have the sense that it would increase the measure of safety if we let the pharmacists rather than the individuals drive these retail sales over the Internet? Oregon, for example, has a proposal Senator Smith and I have been interested in that essentially uses the pharmacist as the hub of the effort to both ensure safety and have oversight. Would that make for a more compelling case for Internet sales, if you used the pharmacist as the focus rather than the individual simply going online and searching for what is out there?

Dr. CARMONA. Senator, if you are saying American licensed pharmacists working in regulated pharmacies in the United States who would partner with Internet companies who were FDA-regulated and sanctioned and we had a pedigree on the drugs that could guarantee the safety, I think that would be a viable option.

Senator WYDEN. I hope if the administration takes that position that the goal posts won't move again and that we will have to find yet another way to get over the bar, because I think what our constituents are frustrated about, Oregon has a proposal right in front of the Federal Government. We haven't been able to even get a meeting with the Federal agencies to talk about it. Every time we get right up to the football, kind of like the cartoon figure, the football gets snatched away. We would like to find a way to do this in a bipartisan way.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you. Senator Craig?

Senator CRAIG. Doctor, thank you for being with us. As I began in a small way to examine this issue a year ago and looked at the briefings of your visit to JFK, I visited with Rudy Giuliani, who was involved in reviewing this, I began to recognize a near impossible task. Let me say this because we are expressing a great deal of concern about safety. The positive-negative here is that the American consumer, when it comes to drugs, has been taught since childhood that drugs are safe——

Dr. CARMONA. Yes.

Senator CRAIG [continuing]. Because they go through a very rigid protocol. We have a phenomenally rigid system for the Food and Drug Administration certification of drugs, the testing. We are not always perfect. We have just seen a few pulled from the market. But we are very, very good and it is very expensive, what we do, that time line and all of that.

Dr. CARMONA. Yes.

Senator CRAIG. So if it is a prescription drug, it has got to be safe. I believe that is the mindset of the average consumer in our country today.

Now they enter into a pure free market environment, the Internet. You have just stated where those websites may send them. They have no idea where it sends them. Websites are phenomenally misleading. It takes a near expert to detect a truly legitimate website versus one that is illegitimate, and my guess is we don't have enough money to hire enough people to build the expertise inside government today to control it and regulate it effectively. These pictures alone of what you saw are a perfect example of a phenomenal problem. How do we deal with it?

Well, I believe safety is the issue. I think that is clearly what the chairman is concerned about, what I am concerned about. As my seniors enter into a free market environment, they put their hands on the keyboard, they go to the Internet. Is it safe? Are they getting a legitimate product? Can we possibly control it? We have been very careful not to step into the business of controlling and shaping the Internet. We have done it very apprehensively as a Congress.

I guess my question to you would be, you testified that to maintain the levels of safety, current U.S. standards would need to be applied to all foreign drug suppliers. First of all, is this possible? What would it take to accomplish this level of standardization internationally?

Dr. CARMONA. Senator, it is possible if you are considering commercial importation. If you are thinking about personal, we believe that would be impossible because there are just far too many points of entry and you would have an open system.

Right now, the system that we have that is the gold standard for the world is a gold system. We know where every medication is manufactured, how it is distributed, how it is packaged. There is a pedigree from the lab right to the patient——

Senator CRAIG. Yes.

Dr. CARMONA [continuing]. That we can assure the safety. Once you open it from a closed system to an open system, we could not sustain that degree of safety.

So if we are speaking strictly on commercial importation, an option would be to consider that, but on a limited fashion, that it wouldn't be open to everybody. It wouldn't be an open system. But you all would define how many portals of entry, who should be involved, what are the standards, but if you do that, then the FDA needs new authorities. The FDA needs new inspectors commensurate with the program that you would build, because right now, they cannot keep up with the volume that is coming in. There is no way that they can ensure safety now, even with a commercial system.

Senator CRAIG. Well, my brief view of it would suggest that your answer is very accurate. There just isn't any way today, unless we gear up in a phenomenal fashion, to deal with this issue, looking at the activity that's going on out there.

I have a son-in-law who his business is in the Internet and shaping websites and working to control product quality and monitoring. He is involved in a company of nearly 1,000 employees now who do nothing but monitor the legitimate use of a label and notifying a website if it is an illegitimate use, and companies are paying big money to secure their trademarks today and he is involved

in it. So I can sit with him at the Internet and move across it and he will say, no, this one is a phony one, Dad. Look at this. You look at this, you look at this, you look at this. He is an expert in the field now. Yet in viewing that, I see this phenomenal volume going on out there that just grows by the hour, not by the day, and therein lies our greatest problem.

Having said that, is there any specific indication that manufacturers will impose quantity restrictions if prescription drugs are eligible for importation? In other words, product A moving out of the United States into Canada to move back into the United States, if that becomes a standardized process, then what is to stop a U.S. company, or any company, for that matter, from reshaping their market if we have caused a market to move in a different direction by actions of this Congress?

Dr. CARMONA. Senator, your point is well taken. We had testimony from various stakeholders who came before us that that could be a problem when dealing with reimportation, that in looking at Canada, for instance, that they have a very small amount of pharmaceuticals globally that supply their country.

Senator CRAIG. Yes.

Dr. CARMONA. If all of a sudden they become the pharmacy for the United States or some part of the United States, or the world, for that matter, we have heard from their health ministry that they could not do that, that they could not sustain the support of their own people. In fact, during our task force meetings, we had information from the Canadian health minister that they were running into shortages, where some of their people in certain provinces had to be sent to adjacent provinces to get medication because U.S. citizens had already depleted the supplies of the Canadian medications.

Senator CRAIG. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Nelson.

Senator NELSON. Thank you, Mr. Chairman. Mr. Chairman, I am going to have to get a cushion to sit up in these chairs. [Laughter.]

You have got me sitting on the floor here. [Laughter.]

Senator CRAIG. Just a moment—— [Laughter.]

Full-service committee here.

Senator NELSON. That is great. I am curious. Under the existing law, there can be reimportation of drugs from Canada if certified that they are safe by the Secretary of HHS. What role do you play in the certification of the safety?

Dr. CARMONA. Senator, I really play no specific role. My role was as the chair of the task force. As it relates to the regulation of the movement of pharmaceuticals, the Surgeon General has a peripheral role as he would in any issue that affects the health and safety of the United States. But I have no authority in that area.

Senator NELSON. Why do you think that the Secretary would be withholding his approval of the safety of these drugs that would be coming from licensed pharmacies or distribution centers, as Senator Wyden has suggested?

Dr. CARMONA. I don't know that I can answer on behalf of the Secretary, not having asked him that question specifically, but from my standpoint, the issue may be broader than that. As during President Clinton's administration when Secretary Shalala was

challenged with this and now when Secretary Thompson was, both of the Secretaries felt they could not certify safety for the same reasons, that the universe was far too large and we didn't have enough inspectors to be at every portal 24 hours a day and every individual to guarantee safety.

Now, we have stated pretty clearly within our report that if Congress chose to consider some form of limited commercial importation from those sites who are well known, FDA regulated, pedigree of the medication known, then that certainly is an option, but we also provided information to suggest if you do that, here are the cost implications, the economic implications of such a program.

Senator NELSON. Would that meet with your approval from the safety standpoint?

Dr. CARMONA. Sir, any program that you all would support that takes into account the issues that we pointed out in the report, that is safety first, yes, sir, I would have no problem with looking at that. But again, I would reserve my final opinion for when I saw what the proposal was and when and if Congress asked me to render that opinion.

Senator NELSON. What about the program in the State of Illinois?

Dr. CARMONA. I have met previously with the Governor in the State of Illinois. I don't remember the specifics. If you want me to address any of the specifics, please let me know, but I don't remember any of the specifics of that program, because as you well know, across the border and through many States, there are many, many programs, all of which have some particular nuances. So before going on record, I would like to see specifically, and then I would be happy to address those issues.

Senator NELSON. Mr. Chairman, is this a new way of telling me my time is up? [Laughter.]

The CHAIRMAN. It is another way, I guess, but you do have more time. I don't know if anybody is hitting the lights, but—oh, thank you. They are back.

Senator NELSON. Well, in the Illinois case, it is my understanding that participants are saving upwards of 25 to 50 percent of the cost. How do you explain that success?

Dr. CARMONA. Sir, again, I would have to look at the specifics of the program, but generally when we see programs like this, there are individual successes that can be reported. The confounding factors, variables that haven't been looked at, though, are sometimes there is a comparison between patented medications where generics could be substituted, is one example. So the public is not always well informed of the options before them, to use generics, to ask a physician for a generic prescription, that may be in their own backyard. Through comparison shopping, drug discount cards, they may get the same or better benefits.

So often, it is difficult to compare the programs, because as I said, there are such nuances in each of them and the populations are uncontrolled. From my standpoint, I am looking at it from the safety issue and then the cost effectiveness to follow.

Senator NELSON. I want to give you some unsolicited advice.

Dr. CARMONA. Yes, sir.

Senator NELSON. This is kind of like prohibition. We thought the evils of this drink that drive men out of their homes into deprivation, that split up families and so forth and so on, and so a constitutional amendment was passed. The fact was is that the people weren't going to agree with this constitutional amendment, in this particular case the law, and so it was ultimately repealed.

What you have is a situation that you have an unequal force out there and that is drugs across the border that are much cheaper than here, and you have an extraordinary need by senior citizens. Sooner or later, the equalization—it is almost the law of physics is going to occur unless we realize and update the law.

Dr. CARMONA. Yes, sir.

Senator NELSON. Instead of the fiction of just saying that they are unsafe, there has got to be a way that people can come together instead of just for protection of a particular interest, economic interest, and say that there is a greater good here, and that is to find the common denominator whereby we can lower the cost of drugs so that people who depend on them for their livelihood and do not have the financial means, that we can get them.

Dr. CARMONA. Yes, sir.

Senator NELSON. I think that this is just one manifestation of the problem, is the differential between Canada and the United States. I think the overall way to look at this is, particularly with regard to prescription drugs for Medicare, is to allow competition in the marketplace, free market enterprise——

Dr. CARMONA. Yes.

Senator NELSON [continuing]. Whereby there can be a negotiation on the price of those drugs through bulk buying. But that is against the law, too, in the law that was passed here a couple of years ago.

So my advice to you is, we had better start finding a way or ultimately you are going to have just a tremendous reaction in the body politic and it is not going to inure to anyone's benefit unless we do it in an intelligent, methodical fashion.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you. Senator Clinton, Senator Kohl had just stepped out when you came in. You are OK? Senator Clinton, we would also welcome your opening statement if you want to make it.

STATEMENT OF SENATOR HILLARY CLINTON,

Senator CLINTON. Thank you so much, Chairman Smith, but I would just ask unanimous consent to submit my opening statement.

The CHAIRMAN. Without objection.

[The prepared statement of Senator Clinton follows:]

PREPARED STATEMENT OF SENATOR HILLARY RODHAM CLINTON

I'd like to thank Senator Smith and Senator Kohl for convening this hearing on the important topic of prescription drug reimportation, and allowing us to begin discussing this issue for the 109th Congress. I'd also like to thank the panelists for providing testimony to us today.

Today's hearing is my first as a member of the Senate Special Committee on Aging. I'm extremely pleased to have the opportunity to serve on this committee with Senators Smith and Kohl, both of whom have provided great leadership on

aging and senior issues. I look forward to working with all the committee's members to help our nation's seniors.

I know that many of my colleagues on the Aging Committee share my deep concern with skyrocketing prescription drug costs, and are eager to pass legislation to facilitate their safe reimportation as quickly as possible. We had a good bipartisan bill the—Pharmaceutical Market Access and Drug Safety Act—which I was proud to cosponsor last session. I look forward to continuing to work with Senator Dorgan and Senator Snowe on this issue.

I would urge Leadership to help move this legislation as quickly as possible, because as my colleagues on the Aging Committee are certainly aware, our senior citizens need cheaper drugs.

Older Americans pay higher prices for the exact same prescription drugs being taken by their counterparts in other industrialized countries. The Congressional Budget Office has found that prices for brand name prescription drugs are 35%–55% higher in the United States.

Seniors, many of whom are on fixed incomes, are finding that their prescription drug costs just keep increasing. The price of medications is rising faster than inflation, and our seniors end up spending larger portions of their income on drugs.

In a recent American Association of Retired Persons (AARP) survey, 71% of seniors said that paying for prescription drugs posed a financial problem for them.

The increasing cost of these drugs means that many of our seniors face tough choices about their health, choices that no one should have to make. We've all heard stories about seniors who try to stretch their dosages by splitting one pill over two days, or seniors who have to choose between buying food and getting a prescription filled. I think it's unconscionable that our health care system forces seniors to make these choices.

Because of these high prices, many seniors are willing to take any measures to access cheaper drugs. For seniors in border states like New York, a logical choice is to purchase drugs from places like Canada, where safe, high-quality drugs are available at cheaper prices—prices about 1/3 less than what they could find at the local drugstore.

I have constituents like Jeanne Brennan, a 73-year old retired nurse from Manhattan, who has a monthly drug bill of $450. She needs her medications to help control her high blood pressure, arthritis, and ulcers. She buys drugs in Canada because it makes economic sense—a three-month supply of her arthritis drug costs $163 in Montreal, as opposed to the $654 it would cost her in the United States. A senior on a fixed income with multiple health needs should have access to this kind of savings without having to go to Canada.

I believe we need to help our seniors get the lowest possible prices for their medically necessary treatments. We need to make drug reimportation safe, we need to make drug reimportation safe, we need to make drug reimportation unambiguously legal, and we need to so do as quickly as possible.

We also need to make sure that the many seniors who do go online to purchase drugs can do so safely, and the legislation that Senators Dorgan and Snowe will introduce in the 109th Congress will help create a safe environment through which seniors can purchase drugs over the internet, and I look forward to supporting these efforts.

Indeed, the Dorgan-Snowe legislation contains many provisions that will ensure safety while giving seniors access to cheaper drugs. This bipartisan bill will allow seniors to safely access drugs from Canada starting 90 days after enactment. It will provide the needed authority and funding to the FDA to regulate foreign pharmacies and wholesalers, so that we can be sure that any drugs that enter the United States are safe for our seniors. It will increase the consumer protections involved with internet pharmacies, so that seniors who don't live near the border can access imported drugs without being defrauded.

Senator Smith and Senator Kohl, thank you again for convening a hearing on this important topic. I look forward to learning more about this issue from our panelists today.

Senator CLINTON. I have to express my delight on joining this committee and serving with you and Senator Kohl and I look forward to the work of this committee. I must confess that with the low height of the chair and the lights going off, I thought maybe I was in a test about how quickly I am aging, you know, whether I can get up out of a low chair and see what is going on——[Laughter.]

Which is something that, I guess if that goes with committee membership, I will do my best.

Senator CRAIG. It does. [Laughter.]

Senator CLINTON. I guess I would also ask unanimous consent that I, too, have a chair pillow next time, too, Senator Craig. I changed chairs, so I am fine.

The CHAIRMAN. We will add some pillows. [Laughter.]

Senator CLINTON. I want to thank both Senators Smith and Kohl for convening this hearing because it is such an important topic. The issues it raises really do go to the heart of the expectation, as Senator Craig eloquently stated, that Americans will be able to trust their prescription drugs.

On the other hand, it also goes to the point that Senator Nelson was making, which I think Secretary Thompson in a sense conceded last year when he said that legislation for drug reimportation was inevitable and it will happen either under our control or out of our control after a lot of damage has been done because of the breakdown in the system, because of Internet purchases and the like.

So I really commend you for holding this hearing because we need to shed a lot more light on this matter and try to come to a consensus about how we intend to proceed.

I appreciate the Surgeon General being here and also for your leadership on the HHS task force. As I read the task force report, I think that it clearly states the issue, and the conclusion of the task force members is that the task force believes that access to drugs that are safe and effective, as well as affordable, is a critical policy goal and that all approaches to achieving this challenging goal should be explored thoroughly. I very much agree with that.

I have worked with several of my colleagues in introducing a framework for implementing safe importation of prescription drugs. Senators Dorgan and Snowe have taken the lead on this. Does the task force or does HHS have a position on the Dorgan-Snowe reimportation bill?

Dr. CARMONA. Senator, from the standpoint of our task force, we took no position on any bills. Our goal was to answer the questions and provide you the best information for you to make your decisions. But I think the statement that you read truly reflects the task force in a unanimous way, that we really understand the dynamics here and the complexity of this issue, but every and all opportunities need to be explored.

Senator CLINTON. General, I would appreciate your reviewing the Dorgan-Snowe legislation because what we attempted to do, and really Senators Dorgan and Snowe deserve the credit for this, was to deal with the concerns outlined in Secretary Shalala's letter that you referenced earlier, because when the Congress did pass legislation asking that importation, reimportation take place, President Clinton tasked Secretary Shalala with responding to that. Her December 26, 2000, letter reflects some of the difficulties that tied up the negotiations. There were a lot of concerns on the part of different Members of Congress with different stakeholders at the table.

What the Dorgan-Snowe legislation tries to do is to deal with the labeling issue by requiring that commercial shipments of drugs to

importers be labeled with FDA-approved labeling, dealing with the discrimination issue by making discrimination against foreign distributors and pharmacies illegal and imposing treble damages, dealing with the timing issue without having a sunset, because one of Secretary Shalala's biggest problems with the legislation that was being proposed back in 2000 is that it was sunsetted. So that doesn't provide certainty to anyone.

I mean, part of our job legally, legislatively, regulatorily, is to look at legislation, figure out how it is working, and make improvements or solve problems, if necessary. But if you put a sunset on it from the very beginning, that doesn't provide much of an incentive.

Finally, providing sufficient funding, an issue that is a critical one as to how we would police such a system, and in the Dorgan-Snowe legislation, there is a requirement that each importer and exporter pay a one-time registration fee of $10,000 and semi-annual inspection fees capped at one percent of the total price of drugs so that we can use those dollars to enhance the inspection process, hire the necessary people.

We are going to spend the money one of two ways. We are going to spend the money going after counterfeiters trying to deal with Internet problems, as Senator Wyden pointed out, or we are going to spend the money trying to get a system in place that we then can regulate.

So I would appreciate very much, General, that you provide a response with respect to the Dorgan-Snowe bill. I look forward to the new Secretary of Health and Human Services also working on this issue because the inevitability of it is clear to all of us. The problems are clear to all of us. I think that there are enough people of good faith and intelligence to figure out how to deal with this.

So I thank you for taking on this task force, but we need now to move beyond the inevitability and the belief of the task force members to actually find some solutions.

Dr. CARMONA. Thank you, ma'am.

Senator CLINTON. Thank you.

The CHAIRMAN. Thank you, Senator Clinton.

Senator Kohl.

Senator KOHL. Thank you. I will just make one observation and ask for your reaction.

Dr. CARMONA. Yes, sir.

Senator KOHL. I think the American people are rather perplexed with this whole issue for many reasons, but the thing that comes to mind with me is that we are importing and ingesting food stuffs all over the country and have been for many decades, whether it is fruits and vegetables, poultry, beef. Enormous amounts of things that are brought into this country under standards of inspection and as much safety as we can impose on the system are bought and put into our systems every day and we have managed to set up a process that, for the most part, works.

Why would pharmaceuticals fall totally outside of that ability that we have to control other imports?

Dr. CARMONA. Well, sir, I don't know that they fall totally outside. It is a slightly different market if you are deciding to eat a

certain food that may be imported from another country versus a medication that is going to be life-saving or prevent a disease.

However, philosophically, I think the approach is the same, and as we pointed out in the task force report, there can be systems set up for commercial importation that would allow that to occur. We believe that they would have to be much more stringent than just usual food products that are coming in and out that we are mostly looking at for the purpose of safety and were they refrigerated and processed appropriately so that the American public is safe of any disease. We have the added threat today of the new threats upon us of terrorism and the fact that that presents a new challenge to us.

But notwithstanding that, we do agree that there are options to set up systems that can be well-defined and considered a closed system to ensure the safety of the American public. We also add, and we had recommended to Congress that if you consider such a system of importation that is well defined, prospectively determined, and regulated by FDA guidelines, that you consider the economic implications both short-term and long-term, and we had very robust discussions about that with world economic leaders to find out just what would be the implications of such.

But I am in agreement with you. It can be done.

Senator KOHL. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. To Senator Kohl's point, General, I have one follow-up. As I read your report, you estimated the cost of setting up a system was $3 billion. But that was using, as I understand it, existing authorities. What I took from that is that estimate did not take into account the cost savings of setting up additional authorities or new approaches specifically to regulate Internet pharmacies. Was there an inclusion of such new authorities in that cost or is it limited to traditional types of border inspections that——

Dr. CARMONA. This was for personal importation and encompassing a great deal of factors, but this was a number that was generated in some of the discussions with our stakeholders as more or less a best guess.

We recognize that the cost variables and the incremental variables leading up to a total cost will be entirely dependent upon what Congress determines is an appropriate system. I think once you all, if you embark on that path, decide on a certain system, we can work back with you to give you cost estimates at that point. But right now, without a true definition of what a system would look like, it is very difficult to put a price tag on that, although we recognize it would be very expensive.

The CHAIRMAN. Well, to Senator Clinton's point, we are going to pay for it one way or the other——

Dr. CARMONA. Yes.

The CHAIRMAN [continuing]. We are going to pay for it in poor health, bad medicine. We are going to pay for it in criminal interdiction. So it seems to me that an Internet registry where people wanting to be legitimate players could qualify, and seniors could be alerted to the availability of a safe place to do importation, that that should, frankly, with technology, greatly reduce the cost from $3 billion.

Senator Wyden.

Senator WYDEN. Thank you, Mr. Chairman. I just wanted to ask one additional question.

I think you heard me, Doctor, go through this problem of the significant price spike we have seen in prescription medicine just in the last few weeks. Lipitor is up 5 percent, for example. Lipitor is a blockbuster drug. Now since you in your testimony talked about the prescription drug bill and its impact on cost containment specifically, I would be interested in your thoughts as to why prescription drugs have spiked up so dramatically in the last few weeks. I wouldn't have asked you this question unless you put the topic in play in your testimony, but I came concerned about the price spike. I noted your comments in your testimony. I would be curious, your thoughts about why prescription drugs have soared yet again in the last few weeks.

Dr. CARMONA. The spike that you are speaking of, I am aware of only through the media. We haven't studied that spike. The question of cost of prescription drugs and why there was a perception of the American public bearing an unfair share of that cost is one that we did discuss during the task force and received a great deal of testimony from economists as well as from the drug industry and many stakeholders who had expertise in the area. A lot of it was fueled by the issue of the cost of research and development, the time it takes from bench to the market for a drug being 15 to 20 years at $800 million per drug and maybe only 20 percent of the drugs make it, so there is a huge overhead even for your failures. That was one component.

Senator WYDEN. But that is year in and year out, Doctor.

Dr. CARMONA. Yes.

Senator WYDEN. I don't want to belabor this, but I know the Wall Street Journal, has said that possibly one of the factors in the price spike in the last few weeks has been that companies are maneuvering given the fact that the bill is about to kick in. Do you see that as a factor?

Dr. CARMONA. Sir, it very well could be, but I have no knowledge. I would be guessing right now since I have not studied that. The only factual information I could give you is what we have studied within the task force report, which is why I reverted my answer back to what we had found.

Senator WYDEN. Your testimony said that the law contains provisions to hold down costs. So you obviously have been looking at the cost containment issue. What provisions in the law contain costs? I ask you that as somebody who voted for the bill. I would be interested in your thoughts as to what provisions in the law contain costs.

Dr. CARMONA. Well, the open market, first of all, is maybe one of the best ways to contain costs and foster competition. So any provisions that we have that would allow for open market competition, I always think would be in the best interest of the American public. When we begin to manipulate markets or have price controls in one sector and not another, it becomes very difficult then to start comparing. You are comparing apples and oranges.

I mean, it is deceivingly simple to say that let us bring in a drug from Canada because it is cheaper. That is OK, but again, not being the expert but asking the questions at the task force with my

task force was, well, what are the implications of not just one but millions of drugs flowing across the border, not just today, but next year and in 10 years? What will happen to our markets? Is this going to hurt us in the long run even though it may help those in need today?

That is the information that we solicited and have in this report. Outside of that, I was not asked to look at or study those issues, and specifically the spike in the last couple of weeks. I don't have that information, sir.

Senator WYDEN. You have got six United States Senators here who are not exactly a price controls caucus. I mean, we are, all of us, Democrats and Republicans, talking about marketplace approaches, and yet we just don't seem to be able to get anywhere with the administration in terms of advancing ideas that will allow us to do it. But Senator Snowe and I will be taking another crack at it next week.

Dr. CARMONA. Yes, sir.

Senator WYDEN. The Medicare program is not even doing what smart private sector buyers are doing when it buys medicine. Every private sector buyer who buys in volume says, "Look, here is an opportunity to get a better deal if I am buying in volume." This is not a government program. This is what Weyerhauser does or an auto company does or a hardware store or anybody else. So when you said in your testimony that the law contains provisions to contain that cost, there has been a price spike in the last few weeks with respect to medicine. I would like to see what we are going to do with it on a bipartisan basis and I hope we can continue to work with you in that regard.

Thank you, Mr. Chairman.

Dr. CARMONA. Thank you, sir.

The CHAIRMAN. Senator Nelson has an additional question.

Senator NELSON. Dr. Carmona, is it the policy of the administration to allow a 90-day supply of prescription drugs to be imported from Canada for a senior citizen?

Dr. CARMONA. There is an FDA discretionary policy that was put into effect some years ago that would allow certain medications that are maybe produced in another country and known to be safe to the FDA and are needed, for instance, for a cancer therapy or such by a citizen to do so, but small amounts for their personal use only. It was always thought of as a courtesy to certain people who may be traveling overseas.

Historically, as we looked at it, I guess in the 1990's or so as Internet pharmacies popped up and the trade in pharmaceuticals cross-border really started to become quite robust, it became a problem and questions were posed regarding that discretionary policy because people were taking advantage of it.

Senator NELSON. So, in fact, via the Internet or by mail or by telephone, you are saying that it is or is not the policy now that is allowed for a 90-day supply of prescription drugs to be imported from Canada for personal use?

Dr. CARMONA. As I said and I think is reflected in the report, there is a discretionary part of the law which allows for certain products that people would need, and I think, as I said, historically, when we looked at this, certain products that were available

overseas that were approved that might not be available in the U.S. but that we knew were safe could be bought in a limited fashion for personal use, and I think that is the 90-day exception you are speaking of. I just want to make sure that I am addressing your question specifically.

Senator NELSON. Well, the FDA has issued a statement that says that they are going to allow a 90-day supply for personal use to come in from Canada, and I want to make sure that this is squaring with your position as the Surgeon General.

Dr. CARMONA. My understanding, sir, is that those were products that were available out of the U.S. that were deemed to be safe and necessary for the health of that individual. From my standpoint as Surgeon General, whether it is Congress considering a new program or an existing program, the first question I would ask is, is this safe? How do we know the pedigree of the medication? Where was it made? Who packaged it? Who is selling it, and so on?

Senator NELSON. All right. When these drugs are seized, is it the policy of the administration that a notice must be given to the receiver of the drugs that they have been seized?

Dr. CARMONA. My understanding is that a notice is given to the sender, and if there is any question as to the authenticity or the legality of the shipment that they are given a window of opportunity to respond and provide evidence that this is indeed a legal shipment of a medication. If not, those medications remain confiscated and are sent back to the sender.

Senator NELSON. Well, I want to give you an example of the trauma that one of my constituents from Florida went through. Ms. Jean Eads of Mount Dora, FL, had ordered by the Internet, had used her Master Card, was charged $276 through a Canadian pharmacy called Avcare. Her drugs were seized along with a big shipment, so she is out $276. She doesn't receive the notice, which, by the way, is required under law, under U.S. code. She needs her medication. For her to purchase the same medication in the United States, it is going to cost her twice as much and, of course, she is a senior citizen on a fixed income.

Now, this is the kind of personal experience that is happening day in and day out and we have got to get it corrected. But for the fact that she wrote her handy-dandy Senator and that I got into it and jumped on it with all fours and finally shook enough of the bureaucracy loose so that we found the drugs, otherwise, she would have been out drugs, she would have been out $276, and she couldn't afford any of that. What is hanging in the balance is her health and that is what we have got to correct.

Dr. CARMONA. Senator, I couldn't agree with you more and I think that your statement really bespeaks the fact that if Congress decides that we want to have a legalized system of importation, that it has to be closely regulated, because as we found when I visited the JFK center, these packages, hundreds and hundreds of them, come from all over the world. The Federal investigators confiscate them because often they don't have labels. They are not what they are purported to be. So sometimes we look and there may be a question. They are not sure. Is this good or not? They are going to err on the side of public safety.

But with a well-regulated system that you all would empower the FDA to oversee for commercial importation, that goal, which is desirable to us all, is achievable.

Senator NELSON. Let me just conclude, I guess, Doctor, and thank you for your public service.

Dr. CARMONA. Thank you, sir.

Senator NELSON. When all of this was occurring a year ago or so, did you hear in the administration there was an attempt to get the credit card companies to back-check on who is charging for prescription drugs in Canada and to stop it? Did you ever hear of that?

Dr. CARMONA. No, sir, I am not aware of that.

Senator NELSON. Well, it did happen and the FDA finally rescinded that, as well as—well, the FDA has backed off of that warning. But they did. They, in fact, put out that kind of warning. As a matter of fact, one of our colleagues from Minnesota, if he hadn't gotten into it, Senator Dayton, there were a group of senior citizens that had gone across the Canadian border to buy drugs coming back into Minnesota. Customs boarded their bus and started confiscating their prescription drugs. Only because, again, the intervention of a United States Senator did that get worked out. But this is the kind of nonsense that is going on for poor people that need help.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

General Carmona, thank you. You have been very forthcoming and answered our questions. We thank you for your service, for your report and your presence here today.

Dr. CARMONA. Thank you, sir.

The CHAIRMAN. With that, we will call up our next panel, a very distinguished panel. First is Jeffrey Kimmell of drugstore.com; Gary Schnabel, my constituent, from the Oregon Board of Pharmacy; Mary Jorgensen—I believe Senator Kohl will introduce Ms. Jorgensen; and Roger Pilon of the CATO Institute.

I would indicate for members there is scheduled to be a vote at 11:30. We would briefly recess and reconvene here if, in fact, we don't conclude. But that vote may be pushed back, as well.

We will proceed starting first with Jeffrey Kimmell.

STATEMENT OF JEFFREY KIMMELL, R.PH., VICE PRESIDENT, HEALTHCARE SERVICES AND CHIEF PHARMACY OFFICER, DRUGSTORE.COM, INC., BELLEVUE, WA

Mr. KIMMELL. Mr. Chairman, my name is Jeff Kimmell. I am the Vice President of Healthcare Services and Chief Pharmacy Officer at drugstore.com. I am a licensed pharmacist and I have been involved in the pharmacy business for more than 30 years.

I want to thank you, Chairman Smith and Ranking Member Kohl, for your leadership and for holding this hearing today. We share your concerns about the safety of millions of consumers who purchase prescription drugs over the Internet.

Congress needs to regulate appropriately, establish clear rules that protect consumers, and prevent Internet shopping for prescription drugs from becoming an uncontrolled free-for-all. Since its inception, my company, drugstore.com, has taken the high road, im-

posed high standards and submitted to voluntary third-party review. But too many others have not.

There are three sections to my remarks today and I encourage you to review the written testimony for more detail. First, I will tell you about the general benefits of online pharmacies. Second, I will provide additional detail about VIPPS, a voluntary certification standard, and how that can serve as the basis for a single national standard for online pharmacies. Finally, I will offer some insight into how Congress might provide appropriate enforcement authority to any legislation designed to protect consumers.

Before going into the details of these remarks, I would like to note that many of these ideas reflect provisions in bills previously introduced in the 108th Congress by Senators Judd Gregg and Gordon Smith and Representatives Greg Walden and Jim Davis. The drugstore.com web store is a leading online retailer. Our pharmacy is licensed to dispense medications in all 50 States.

Licensed online pharmacies, such as drugstore.com, do provide a safe, efficient, and cost-effective alternative to more expensive brick-and-mortar pharmacies. The Internet business model operates with less overhead than a typical retail chain, allowing us to offer prescription drugs up to an average of 20–30 percent off the prices typically offered by U.S.-based bricks-and-mortars.

It is also a little known fact that our generic drug prices are significantly better—often 50 percent less—than those of most foreign-based competitors.

In addition, we offer our customers online e-mail drug recall alerts, an extensive drug price index that allows for easy comparison shopping, a detailed drug information data base, and a variety of other specialized customer care features that are detailed in the written comments.

But drugstore.com does more than provide good service at affordable prices. We practice good pharmacy. We are fully compliant with the Health Insurance Portability and Accountability Act of 1996.

We respect and honor the sanctity of the patient-physician relationship and adhere to American Medical Association policy by requiring patients to see a physician before doing business with our pharmacy.

We accept prescriptions only from licensed health care providers. We do not prescribe medications or otherwise practice medicine. Like traditional retail and mail service pharmacies, we accept, verify, and cross-check all prescriptions. Consumers can identify whether an Internet pharmacy adheres to a variety of standards associated with good pharmacy practice by looking for the Verified Internet Pharmacy Practice Sites, or VIPPS®, seal. VIPPS is a voluntary program developed by the National Association of Boards of Pharmacy, or NABP, in conjunction with a coalition of State and Federal regulatory associations, professional associations, and consumer advocacy groups. A list of detailed verification procedures is included in the written testimony.

To ensure reliability and safety, drugstore.com strongly supports a single, national standard for online pharmacies and advocate that, in order to legally sell pharmaceuticals online, all Internet pharmacies should be required to meet such a uniform certification

standard. Based on our experience in complying with the stringent requirements of the VIPPS certification process, drugstore.com believes that VIPPS can and should be the basis for a federally mandated program. We encourage Congress to move in this direction as soon as possible.

Certification, however, isn't enough to effectively stem the tide of rogue online pharmacies and ensure the integrity of our drug delivery system. Any certification standard must be backed up with clear lines of enforcement authority. The following outlines one approach that, we are convinced, would discourage illegal Internet pharmacies before consumers are put at risk:

First, make it illegal for online pharmacies to advertise on Internet search engines unless they meet the approved certification standard.

Second, stop credit card payment to pharmacies that do not meet the certification standard criteria, to stop funding at the source.

Third, motivate third-party shippers to refuse shipments from pharmacies who do not meet the certification standard.

As a final point, there are multiple layers of jurisdiction regarding oversight and enforcement of our nation's drug delivery system. We suggest consolidation or coordination of efforts, and encourage you to carefully examine the existing legal and regulatory structure and its adequacy to address the rogue Internet pharmacy problem.

As the U.S. Congress looks for ways to keep the Internet a safe, drugstore.com stands ready to act as a resource. U.S. consumers should feel confident that the online marketplace is safe and secure, especially for purchases that are as important to public health as prescription drugs. We are confident that a uniform certification process and the three-tiered approach to enforcement outlined above would most effectively address this growing public health problem. Thank you for providing us with the opportunity to offer this testimony. I look forward to answering any questions you might have.

The CHAIRMAN. Thank you very much, Jeff, for your testimony and for your work.

[The prepared statement of Mr. Kimmell follows:]

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January 26, 2005

SENATE SPECIAL COMMITTEE ON AGING

Testimony submitted by Jeff Kimmell, RPh
Vice President, Healthcare Services & Chief Pharmacy Officer
drugstore.com, inc.

Mr. Chairman, my name is Jeff Kimmell. I am the Vice President of Healthcare Services and Chief Pharmacy Officer at drugstore.com, inc. I'm a licensed pharmacist and I've been involved in the pharmacy business for more than 30 years. When I was 13, I started working with my father at the drugstore where he worked. During my career, I have been involved in nearly every aspect of pharmacy operations, in settings ranging from mail order to retail to the Internet.

I want to thank you, Chairman Smith and Ranking Member Kohl, for your leadership and for holding this hearing today. We share your concerns about the safety of millions of consumers who purchase prescription drugs over the Internet. There is little doubt that as consumers increasingly bear the burden of paying for prescription drugs, they will turn to the Internet for cost-effective alternatives. It's our job—yours as legislators, and ours as advocates for Internet pharmacies—to ensure that we're doing everything we can to protect consumers in this process.

I am here, and my company is here, to help ensure that consumers have freedom of choice in obtaining their goods and services from the Internet, and that this important tool remains a viable, reliable, safe, secure, private, cost-effective, and trustworthy choice. Congress needs to regulate appropriately, establish clear rules that protect consumers, and prevent Internet shopping for prescription drugs from becoming an uncontrolled free-for-all that ultimately harms consumers. Since its inception, my company, drugstore.com, has taken the high road, imposed high standards and submitted to voluntary third-party review. But too many others have not made an investment in safe pharmacy practice.

There are three sections to my remarks today. First, I'll provide some brief background about drugstore.com and articulate the general benefits of online pharmacies. I will use drugstore.com as a "case study" of the steps that legitimate pharmacies take to add value to, and reduce costs for, consumers. Second, I'll provide additional detail about VIPPS, the voluntary certification standard with which we comply, and how that can serve as the basis for a single national standard for online pharmacies. Finally, I'll offer some insight into how Congress might provide

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appropriate enforcement authority to any legislation designed to protect consumers from unscrupulous Internet pharmacies.

Before going into the details of these remarks, I'd like to note that many of these ideas reflect provisions in bills previously introduced in the 108th Congress by Senators Judd Gregg and Gordon Smith and Representatives Greg Walden and Tom Davis.

Legitimate Internet Pharmacies Can Empower Consumers, Reduce Costs

The drugstore.com™ Web store is a leading online drugstore and information site for health, beauty, vision, and pharmacy products. Our headquarters are in Bellevue, Washington and our 290,000 square-foot distribution center is located in Swedesboro, New Jersey. We offer the convenience of ordering 24 hours a day, seven days a week, with the privacy of both home shopping and home delivery. Since we opened our online store in early 1999, we have served more than 5 million customers and filled more than 2 million prescriptions. From the beginning, we have made a considerable investment in providing our customers with a safe, convenient, private, and informative shopping experience for their prescriptions and over-the-counter consumer products.

Our retail pharmacy is licensed to dispense medications in all 50 states. We undergo a rigorous third-party certification process administered by the National Association of Boards of Pharmacy, in order to assure customers that we have reasonable safeguards in place. From the very beginning, drugstore.com recognized the need for a reputable third-party to develop and uphold standards for online pharmacies in order to ensure consumer safety and confidence.

Licensed online pharmacies, such as drugstore.com, CAN provide a safe, efficient, and cost-effective alternative to more expensive brick-and-mortar pharmacies. For example, filling a prescription at drugstore.com involves quadruple pharmacist checks in the process—many more quality control checks than a retail pharmacist usually conducts. We're able to allocate multiple pharmacists to the same order, which ensures that the checks are made by a different set of "eyes" during each step of the process – again providing more checks than a typical retail pharmacy might deliver.

In addition, we offer our customers online email drug recall alerts in the form of the drugstore.com eMedAlert program. Some of you may remember the most recent Vioxx drug recall. With eMedAlert, drugstore.com Vioxx customers received notice of this FDA recall *within hours* after the FDA made its announcement. This kind of consumer safety alert simply isn't feasible in the brick-and-mortar pharmacy world.

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Technology allows us to automatically cross-check potential drug interactions and easily screen for health conditions that might be potential contraindications for a prescribed medication. We also provide an extensive drug price index that allows for easy comparison shopping, a detailed drug information database, and other specialized customer care features, including:

- Ask Your Pharmacist. This feature allows customers to browse a database of responses from our pharmacists of over 800 frequently asked questions about medications, dosage, delivery systems, common side effects, and other information about prescription drugs and health-related products. In addition, our customers can ask our pharmacists questions that are not answered in our archive. Our pharmacists seek to provide an initial answer to a non-emergency customer inquiry within one business day.

- Reminders. We have the ability to e-mail a customer when a prescription or non-prescription product on his or her list is scheduled to run out (or in the case of OTC products, is on sale), reminding the customer to order a replacement or a prescription refill.

- Private, Secure Access to Customer's drugstore.com Prescription History. Customers who fill their prescriptions at the drugstore.com pharmacy can access their secure, individual medication profiles at any time. A written patient information document accompanies all medications dispensed to drugstore.com customers. This service enables customers to maintain a record of their prescription purchases for clinical, insurance, and tax reporting purposes.

- Consumer Drug Interaction Checker. Consumers can use this feature to research interactions among prescription drugs, herbal supplements, and dietary supplements, as well as to identify ingredient duplications between drugs. The checker also allows consumers to search for potential interactions between medications and food, alcohol, and tobacco products.

- Generic Insider. We notify customers if a branded drug becomes available in generic form or if a prescription drug becomes available in a non-prescription form over the counter.

- Privacy. When shopping at a physical store, many shoppers feel embarrassed or uncomfortable buying items that may reveal personally sensitive aspects of their health or lifestyle to store personnel or to other shoppers. Shoppers at the drugstore.com Web store avoid these problems by shopping from the privacy of their home or office and are able to

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ask a drugstore.com pharmacist questions that they may otherwise feel uncomfortable asking in a public place.

In addition to enhanced service features, we believe that there is an important role for legitimate Internet pharmacies like drugstore.com in reducing health care costs. The Internet business model operates with less overhead than a typical retail chain, allowing us to offer prescription drugs up to an average of 20-30 percent off the prices typically offered by U.S.-based brick-and-mortars. It's also a little known fact that our generic drug prices are significantly better – often 50 percent less – than those of most foreign-based competitors.

The drugstore.com Commitment to Quality and Safety

Legitimate online pharmacies such as drugstore.com are an important part of the daily lives of an increasing number of Americans. We are serving the growing numbers of online consumers by providing a safe, reliable, cost-effective, innovative, interactive, and personalized service features such as those described previously. We are fully compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which established national standards to protect the privacy and security of personal health information.

We respect and honor the sanctity of the patient-physician relationship, and adhere to American Medical Association policy by requiring patients to see a physician before doing business with our pharmacy.

Our full-service pharmacy stocks more than 4,800 prescription drugs. The pharmacy services at the drugstore.com online pharmacy are provided by experienced professionals using sophisticated information technologies. We accept prescriptions only from licensed health care providers. We do not prescribe medications or otherwise practice medicine. Like traditional retail and mail-service pharmacies, we accept, verify, and cross-check prescriptions. The following outlines some of our extensive protocols:

- Accepting Prescriptions. For new prescriptions, customers can mail their prescriptions to us or direct their physicians to call in or fax their prescriptions to us. For transferred prescriptions, customers can direct their pharmacy to transfer their prescription to the drugstore.com pharmacy or request that we contact their pharmacy to transfer the prescription. Customers may order refills from us through our Web site or over the telephone or respond to one of our e-mail prescription refill reminders. For renewal prescriptions, customers may also request that we contact their physician directly to obtain prescription information.

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- Verifying Prescriptions. Our pharmacists verify the validity and completeness of prescription drug orders using methods similar to those used by community-based pharmacists. The standard practice for verification of prescription drug orders is for the pharmacist to contact the physician's office by telephone or fax if there is any reason to question the prescription's validity, accuracy, or authenticity. In addition, our pharmacists call and verify the validity of prescription drug orders for controlled substances that we fill. Our pharmacists also verify that all legally required information is recorded on the prescription drug order and, as necessary, use a database of physician-identifying information to confirm the validity and accuracy of the prescription.

- Drug Utilization Review. We ask all customers who use our prescription drug services to provide our pharmacists with information regarding drug allergies, current medical conditions, and current medications. Our pharmacists use technology-aided processes to check and cross-check every prescription against the information we receive from the customer for drug, disease, and allergy interactions.

These procedures represent the basics of sound pharmacy practice. Consumers can identify whether an Internet pharmacy follows them by looking for the Verified Internet Pharmacy Practice Sites, or VIPPS®, seal. This voluntary program was developed by the National Association of Boards of Pharmacy (NABP) in conjunction with a coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups, and is currently administered by the NABP. The NABP introduced this program in 1999, in response to public concern about the safety of pharmacy practices on the Internet.

To ensure reliability and safety, we strongly support a single, national standard for online pharmacies and advocate that, in order to legally sell pharmaceuticals online, all Internet pharmacies should be required to meet such a uniform certification standard. Based on our experience in complying with the stringent requirements of the VIPPS certification process, we believe that VIPPS can and should be the basis for a federally mandated program. We encourage Congress to move in this direction as soon as possible.

According to the National Association of Boards of Pharmacy, the VIPPS program:

- Provides important quality and credibility information for both Internet search engines and for consumers. The VIPPS Seal signifies to consumers, and to search engine companies, that the Internet pharmacy holds a valid license, that the pharmacy site has

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been inspected by NABP-approved inspectors, and that the Internet pharmacy's operations meet stringent Internet pharmacy practice standards;

- Is an additional tool to assist regulators in identifying those online pharmacies, located out-of-state, that are lawfully practicing;
- Receives numerous complaints from consumers who have been defrauded by rogue sites located via Internet searches; investigates a variety of consumer complaints about rogue sites; counsels consumers who have been defrauded by rogue sites; and refers rogue sites to appropriate regulatory authorities;
- Has a long history of collaborating with state and federal regulators to investigate and shut down rogue sites. VIPPS was especially active in 2001, when numerous rogue sites were launched to sell Ciprofloxacin hydrochloride (Cipro®) for treatment of anthrax. NABP worked with its members and states' attorneys to identify and report rogue Cipro sites; and
- Is regularly contacted by the Better Business Bureau and financial institutions to verify unknown online pharmacies.

To be VIPPS-certified, an online pharmacy must comply with the licensing and inspection requirements of not only its own resident state, but also for each state to which it dispenses pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to the NABP compliance with other stringent VIPPS criteria, including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.

The VIPPS certification program administrators conduct an extensive licensure review that asks for a list of states in which the pharmacy is licensed or registered, as well as the license or registration numbers. It also asks for verification that all persons affiliated with the pharmacy site, including those affiliated through contractual or other responsible arrangements, who are engaging in the practice of pharmacy (including pharmacists and technicians), are appropriately licensed or registered in good standing in the state in which they practice. The VIPPS program also ensures that there are written policies and procedures for verifying the licensure or registration of new employee pharmacists and, where applicable, pharmacy technicians. This includes asking for details about any person whose license is not in good standing or whose license has been restricted within the past three years.

Additionally, the VIPPS program reviews a wide range of process controls designed to ensure quality and certifies that policies and procedures are in place that:

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- Detail how the pharmacy's policies and procedures are organized, authorized, reviewed, revised, and retired/archived;
- Provide that, in conflicts that arise between individual state laws or regulations and/or between state and federal laws and regulations, the more stringent law or regulation is followed;
- Prevent the prescription drug order from being submitted, honored, and filled by multiple pharmacies;
- Assure that prescription medications are not prescribed or dispensed based upon telephonic, electronic, or online medical consultations without a pre-existing patient-prescriber relationship and an in-person physical examination;
- Assure reasonable verification of the identity of the patient, prescriber, and, if appropriate, caregiver;
- Require patient medication profiles and other related data to be maintained in a readily accessible format organized to facilitate consultation with the prescriber, patient, or caregiver;
- Detail the steps in conducting prospective drug use reviews prior to dispensing of medications or medical devices;
- Ensure patient confidentiality and the protection of patient identity and patient-specific information from inappropriate or non-essential access, use, or distribution while such information is being transmitted via the Internet and while the pharmacy possesses such information;
- Demonstrate that a mechanism is in place for patients to report errors and suspected adverse drug reactions and detailing the pharmacy's response to such reports;
- Provide a mechanism to contact the patient and prescriber if an undue delay is encountered in delivering a prescribed drug or device;
- Inform patients or caregivers about drug recalls;
- Educate patients or caregivers about the appropriate means to dispose of expired, damaged, and for securing and tracing shipments of controlled substances;
- Assure medications and devices are maintained within appropriate temperature, light, and humidity standards, as established by the United States Pharmacopeia, during storage and shipment;

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- Demonstrate compliance with applicable federal and state laws regarding the sale of over-the-counter products identified as precursors to the manufacture or compounding of illegal drugs; and
- Demonstrate implementation of an ongoing Quality Assurance/Quality Improvement (QA/QI) program.

As mentioned previously, the VIPPS certification process is voluntary. Today, about 15 retailers nationwide participate, including drugstore.com and most large national brick and mortar chains with an Internet presence. This, however, is only a small percentage of pharmacies available to consumers through a simple Internet search.

In some cases, non-VIPPS certified pharmacies are indeed bad actors, posing as legitimate online pharmacies, confusing U.S. consumers and providing them with unsafe and illegal prescription drugs, including addictive narcotic drugs. In a June 17, 2004 report presented to the Permanent Subcommittee on Investigations, Committee on Governmental Affairs of the U.S. Senate, the General Accounting Office made clear that many rogue pharmacies are a serious threat to health and public safety. Many bypass the traditional doctor-patient relationship and provide medications without an actual prescription or face-to-face visit. Some provide consumers with pharmaceuticals that are expired, diluted, contaminated, or even counterfeit. At the same time they are jeopardizing public health, these rogue players are taking business away from and diminishing the reputation of legitimate online drugstores like drugstore.com.

Enforcement Mechanisms and Governing Authority

We believe that all Internet pharmacies should be required to meet a uniform certification standard such as VIPPS. We also believe, however, that certification isn't enough to effectively stem the tide of rogue online pharmacies and ensure the integrity of our drug delivery system. Any certification standard must be backed up with clear lines of enforcement authority. The following outlines one approach that, we are convinced, would discourage illegal Internet pharmacies before consumers are put at risk:

- Make it illegal for online pharmacies to advertise on Internet search engines unless they meet the approved certification standard. Prohibit search engines from accepting advertisements from online pharmacies that are not properly certified.

- Stop credit card payment to pharmacies that do not meet the certification standard criteria, to stop funding at the source. The activities of many rogue pharmacies, such as Web sites that offer prescription drugs for sale to consumers without a valid

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prescription, are currently illegal under U.S. law, and should be stopped. Requiring all pharmacies to be certified would establish an incontrovertible national standard for legal operation. Stemming the flow of funds to these sites would be similar to efforts by Congress to starve funding of illegal Internet gambling sites, and would largely help to accomplish the goal of putting illegal pharmacies out of business.

- Motivate third-party shippers to refuse shipments from pharmacies who do not meet the certification standard. One of the benefits of a clear certification standard is that e-commerce enablers (media, payment, and delivery companies) can identify legitimate pharmacies vs. illegal operators.

As a final point, there are multiple layers of jurisdiction regarding oversight and enforcement of our nation's drug delivery system, resulting in confusion over who has ultimate enforcement authority. We suggest consolidation or coordination of efforts.

We encourage you to carefully examine the existing legal and regulatory structure and its adequacy to address the rogue Internet pharmacy problem. Rogue pharmacy Web sites that offer prescription drugs for sale to consumers without a valid prescription, among other questionable practices, are violating *at least* one Federal or state law. Enforcement entities are hampered, however, by a lack of funding and other resources, including state and federal resources for cyber-tracking technology, and a lack of clear jurisdiction over both foreign and domestic operators.

As the U.S. Congress looks for ways to make the Internet a safe place to shop for prescription drugs, drugstore.com stands ready to act as a resource in finding the best solution to this complex issue. U.S. consumers should feel confident that the online marketplace is safe and secure, especially for purchases that are as important to public health as prescription drugs. We are confident that a uniform certification process and the three-tiered approach to enforcement outlined above would most effectively address this growing public health problem.

Thank you for providing us with the opportunity to offer this testimony. I look forward to answering any questions you might have.

Respectfully submitted,

Jeff Kimmell, RPh

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Vice President, Healthcare Services and Chief Pharmacy Officer
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The CHAIRMAN. Gary Schnabel, welcome. It is nice to have you here. I appreciate your traveling this long way.

STATEMENT OF GARY A. SCHNABEL, R.PH., R.N., EXECUTIVE DIRECTOR, OREGON BOARD OF PHARMACY, PORTLAND, OR

Mr. SCHNABEL. Thank you. Thank you, Mr. Chair and Senator Kohl. My name is Gary Schnabel. I am executive director for the Oregon State Board of Pharmacy, located in Portland, OR. I want to thank you and Senator Kohl for the opportunity to appear before the Special Committee on Aging to take part in this discussion of Internet pharmacies and prescription drug importation.

I am delighted and honored to be here on behalf of the Oregon Board of Pharmacy to describe the Board's recent experience in that regard. I am also currently serving as a member of the Executive Committee of the National Association of Boards of Pharmacy, the NABP. My appearance here today is in no way connected with or related to my position or responsibilities with the NABP. I am appearing here solely on behalf of the Oregon Board of Pharmacy and in my capacity as its executive director.

I have submitted a written statement generally describing the Oregon Board of Pharmacy's activities over the past several years in relation to foreign drug importation and Internet drug distribution. With the exception of the Board's work with Governor Kulongoski and his staff on the Pioneer Prescription Drug Project, the Board's experience in Oregon is similar to what State Boards of Pharmacy all across the country have experienced.

I understand the focus of this committee is directed more toward drugs purchased over the Internet than the general subject of drug importation. To that end, I will focus my comments on the Board's experience with the Internet.

The topic of prescription drug distribution via the Internet is a broad and complex topic and a tendency exists to confuse the related public policy issues in the absence of a fairly strong understanding of the terms used in the professional jargon and in the details of drug distribution. To most effectively identify and analyze policy issues that exist, this broad context can be dissected into distinct manageable components.

Those who sell drugs over the Internet fall into one of three categories. They are either pharmacists dispensing drugs through legitimate licensed pharmacies regulated by the State Boards of Pharmacy, they are licensed physicians or other legitimate prescribing practitioners regulated by their State regulatory boards, the Boards of Medical Examiners, Boards of Dentistry, et cetera, or they are neither authorized dispensers nor authorized prescribers.

These individuals in the third category are most deserving of the committee's focus. These are operating fraudulent, rogue websites, deceiving consumers into believing they have some authority to prescribe, dispense, or distribute prescription drugs. These are the sites advertising prescription drugs without a prescription. They may be pharmacists or doctors who are not licensed or who are licensed and operating in violation of the State and/or Federal drug distribution laws. They may not be pharmacists or doctors at all. They may be prescribing real, approved drugs, unapproved imported drugs, counterfeit drugs, or outdated, contaminated, or inap-

propriately manufactured drugs. They may be operating from locations anywhere in the world.

These are the criminal elements that evade the individual Boards of Pharmacy, not only because of the Board's limited resources and authority, but because of the invisibility and anonymity afforded by the Internet. These sites have become pervasive and they can be very professional and convincing in appearance.

The regulation of legitimate pharmacy and medical practice websites currently falls under the jurisdiction of the State professional regulatory boards. The Board of Pharmacy, using the Internet and intending to operate in compliance with the laws of States in which it does business, is no different from any mail-order pharmacy currently licensed by the States that use more traditional forms of communication, such as a telephone, fax, and e-mail. The Internet site is simply a means of communication.

To put it another way, any pharmacy licensed by the Oregon Board of Pharmacy to do business in the State, regardless of its location, can use the Internet as long as it maintains compliance with the prescription recordkeeping, licensing, and professional practice requirements of the Board. The key is not the method of communication. The key is compliance with licensure, recordkeeping, and other professional practice requirements. The Internet has simply made life easier for those who want to violate the law and avoid detection.

If I walked down the street here in Washington or in any city in the U.S., I can tell if the shop I am entering is a pharmacy because of the existing pharmacy regulations. If I go onto the Internet, I cannot tell if the website I see is a pharmacy or not. I think that is the simplest statement of the problem.

The solution would be to create a method by which a person could identify positively whether a website representing itself as a pharmacy was actually a legitimate licensed pharmacy, just as if the person were seeing the sign on the street. The NABP's Verified Internet Pharmacy Practice Site, or VIPPS program, provides one such solution. Only a pharmacy operating in full compliance with State and Federal laws can display the secure VIPPS website seal. Consumers who understand the importance of confirming the legitimacy of a pharmacy website can do so by looking for that seal. Public education is very important in providing this understanding.

Other possible solutions could include mechanisms to require that the credentials of the pharmacy be confirmed before being allowed to display a pharmacy webpage or before credit card payment could be authorized. This is where the Board believes the resources and authority of the Federal Government and Congress is sorely needed. The State Boards of Pharmacy and Medicine can handle the regulation of pharmacies and doctors in the U.S. However, foreign drug sources, legitimate or not, fall outside the States' jurisdiction and the States' regulatory efforts are disabled in the face of the invisibility, anonymity, and covert mobility enjoyed by the operators of rogue Internet sites.

The Oregon Board of Pharmacy has stated that it does not believe Federal licensure or regulation of pharmacies is necessary. The Board believes that if the legitimacy of a pharmacy must be documented or confirmed, it can be done so by or through the State

Boards, where pharmacies and pharmacists are currently licensed and a traditional regulatory mechanism already exists.

The CHAIRMAN. Do I understand, Gary, you are saying that that already exists so that we don't need to reduplicate that cost at the Federal level? What we need to do is have a Good Housekeeping Seal of Approval at the Federal level so seniors know on the Internet they have entered a pharmacy that is safe?

Mr. SCHNABEL. Yes, Senator. If something like that, that would be absolutely correct. I think that information to confirm the legitimacy of those pharmacies does exist in the States currently.

The CHAIRMAN. Is that expensive to do? Would that cost $3 billion to do, as was proposed in the report?

Mr. SCHNABEL. I don't know. I really haven't looked at that. I do know that the process the NABP uses is very effective, but it is a voluntary program. Only those sites who want to display the seal to prove themselves have to do it. It costs, I don't know, what, $3,000 to $5,000 is a guess.

The CHAIRMAN. Wouldn't legitimate players readily want to sign up for a legitimate site and wouldn't there be a presumption for those that didn't sign up that they were not legitimate, that they were selling bad medicine?

Mr. SCHNABEL. Yes, Senator, and that is one of the problems. Because of the costs of becoming certified, the larger legitimate pharmacies that want to be certified and prove they are willing to do that. They are doing business in a number of States or all the States. A pharmacy in Portland who just wanted to put up a website for his or her patients in Portland to reorder their refills, they could do that, too, but they probably wouldn't be able to afford to go through the—they may be a legitimate pharmacy, but for a small pharmacy, that is problematic.

The CHAIRMAN. Have you concluded?

Mr. SCHNABEL. I have just one final comment.

The CHAIRMAN. OK.

Mr. SCHNABEL. The Board of Pharmacy believes that to allow consumers to freely import prescription drugs from foreign sources via the Internet without a massive public education effort would subject consumers individually and the population generally to an unprecedented risk of the introduction of contaminated, counterfeit, or otherwise unconfirmed drug products and provide unprecedented opportunities for the unscrupulous individuals to take advantage of unsuspecting U.S. consumers.

Legislation providing tools to assist in the prevention, detection, and prosecution of the unlicensed, illegitimate prescription drug traffickers over the Internet would be strongly supported and encouraged.

I thank you and I am happy to respond to questions.

The CHAIRMAN. Thank you very much, Gary.

[The prepared statement of Mr. Schnabel follows:]

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Testimony of Gary A. Schnabel, R.Ph., R.N.
Executive Director
Oregon State Board of Pharmacy

Testimony Before the Special Committee on Aging
United States Senate
The Honorable Gordon Smith, Chair
January 26, 2005

Internet Pharmacies and Prescription Drug Importation

Thank you for the opportunity to appear before this committee for the discussion of Internet pharmacies and prescription drug importation. I am delighted and honored to be here on behalf of the Oregon Board of Pharmacy to describe the Board's recent experience with regard to the distribution of drugs via the Internet and the importation of prescription drugs from foreign sources. As described in my curriculum vitae and introductory bio which was provided to your committee staff, I am currently serving as a member of the Executive Committee of the National Association of Boards of Pharmacy (NABP). My appearance here today is in no way connected with or related to my position or responsibilities with the NABP. I am appearing solely on behalf of the Oregon Board of Pharmacy in my capacity as the Board's executive director.

The Oregon Board of Pharmacy was established in 1891 by the Oregon Legislature to administer the first Oregon Pharmacy Practice Act, and has met regularly for this purpose since its inception. The Board, the profession of pharmacy and the manner in which health professions are regulated have evolved significantly in the past 100 years.

Today, the Board of Pharmacy is the sole Oregon agency whose mission and responsibility is to regulate the practice of pharmacy and the quality and distribution of drugs in the state in the interest of the public health, safety and welfare. In this respect, the Board of Pharmacy differs from the other health professional regulatory agencies such as nursing, dentistry and medicine. Not only does the Board of Pharmacy regulate the professional practice of the individual licensees, pharmacists, pharmacy technicians and pharmacy interns, but it also must regulate the various drug outlets involved in the manufacture, storage and distribution of drugs and controlled substances in the state. It is in the context of this responsibility for the quality and distribution of drugs that the Board of Pharmacy has become involved in the drug importation question.

The Board of Pharmacy agrees that patients need and deserve access to necessary safe, effective and affordable medications. It also understands that the method of pricing of pharmaceuticals in the U.S. differs from methods used in many other countries. The U.S. depends upon market forces to set prices while many other governments regulate drug prices. This is, in a nutshell, the reason some drugs are less expensive in Canada and other countries, and why so much interest has been generated around foreign drug importation.

For the past four years the Oregon Board of Pharmacy has been engaged in discussions with its members and staff, and with a variety of external stake holders regarding the cross border sale of prescription drugs. The Oregon Board has also been involved in ongoing research into the legal and safety issues related to the distribution of drugs across foreign borders, in particular, the Canadian border. Initially, the issues revolved around U.S. citizens crossing into Canada to have prescriptions filled at Canadian pharmacies, and around the apparent increase in prescription drug sales over the Internet. The Board's belief was that these activities were in violation of federal law and probably of state law as well. It took the position to monitor the activity rather than initiate any enforcement action, and continue its discussions with and take its lead from the National Association of Boards of Pharmacy (NABP), the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA).

In the summer of 2001 the Board was made aware of a store front business operation in Eugene acting as a "prescription broker", soliciting patients to bring their prescriptions in to have them sent to Canada to be filled. These "brokers" would arrange to have the prescriptions filled in Canada by Canadian pharmacies and mailed directly to residents in Oregon. These businesses were proliferating across the country and appearing in virtually every state. The Board became aware of fifteen such outlets in the state through reports from pharmacists and consumers. It has been estimated the number may actually have been as high as thirty.

Soon, the Board of Pharmacy began to receive complaints from pharmacists, as well as from consumers, about these little understood self proclaimed "middle men". The Board became alarmed at the sudden proliferation of this unregulated distribution of prescription drugs into the state. In March of 2002, the Board issued a press release to alert consumers to the legal and safety concerns. In February of 2003, an article describing the Board's position was published in the Board of Pharmacy quarterly newsletter and placed on the Board's website.

Around the time the Board began to investigate these prescription brokering establishments to determine if they were operating in violation of state law, the FDA, the NABP, state boards of pharmacy and courts across the country were presenting clear policy statements on the legality and safety risks related to such operations. The FDA, state boards of pharmacy and courts began to take action against these entities for violations of state and federal laws.

In October of 2003, the Oregon Board of Pharmacy issued warning letters to a number of prescription brokers identifying the possible violations in which they could be engaged and the potential actions the Board could take for continued violation. As part of its ongoing investigation, the Board issued subpoenas to several of these outlets in an effort to gather information about their business practices. So far, all but one has, on advice of legal counsel, opted to cease operation in exchange for the Board's promise to drop its investigation, rather than respond to the subpoena and let the Board clearly evaluate its operation. The Board is aware of one remaining prescription broker that has not agreed to close. In this case, the Board has proposed disciplinary action in the form of a civil penalty against the business owner pursuant to the Oregon Pharmacy Act. The case is still pending.

The Board has been made aware through various anecdotal reports that a number of Oregon citizens are continuing to purchase prescription drugs through drug distribution sites on the Internet. Some of these Internet sites are legitimate pharmacy operations that remain in full compliance with the laws regulating the practice of pharmacy and the distribution of drugs. Some provide prescription medications without demanding a prescription as required by law. Some are not even pharmacies, but are fraudulent rogue sites pretending to be pharmacies. This has been a cause of concern for the Board because these sites are very difficult to investigate. The legitimate sites make identifying information readily available on the home page. The rogue sites avoid detection by failing to identify names of the doctors or pharmacists and disguising their location while continuing to display an appearance of legitimacy. The Board's compliance staff has been unable to keep up with its normal inspection and investigation work load. There is simply nobody available to investigate these Internet sites beyond a few very cursory initial steps. However, if a complaint is filed against a foreign pharmacy or Internet web site, a full investigation is initiated. The Board's compliance program is complaint driven.

Several suspect Internet web sites have been brought to the Board's attention, but none of these has been thoroughly investigated. Only one complaint has been filed with the Board against a Canadian pharmacy for providing an Oregon patient with the wrong drug. This was a case in which a Portland woman requiring treatment for breast cancer had her prescription filled by a pharmacy in British Columbia. The pharmacy erroneously filled her cancer drug prescription (tamoxifen) with a ninety day supply of a drug to treat high blood pressure (lisinopril). This not only caused a three month delay in her cancer treatment, but the woman suffered a significant adverse reaction, not uncommon to that particular class of drug, that required further medical treatment and follow-up. The impact on the outcome of her breast cancer as a result of this delay and adverse drug reaction may never be known. The Board of Pharmacy attempted to investigate the complaint, but was unable to locate the pharmacist or establish cooperation with the pharmacy. The case was ultimately referred to the investigative agency in BC, the College of Pharmacists of British Columbia. After several months and several attempts to contact the investigator, the Oregon Board eventually received notice that no action would be taken against the pharmacist or the pharmacy.

The Oregon Board of Pharmacy does not believe the long term solution to the complex prescription drug pricing issue lies in Canada or any other foreign country with government price controls. The solution lies in meaningful health care reform legislation that can address existing legal and safety concerns in our own country, and provide affordable access to prescription drugs for citizens at home. Our citizens should not be subjected to the unnecessary risk of unregulated access to medications of unknown quality from foreign countries. Federal and state laws exist to ensure the dispensing of safe and effective medications to U.S. patients. Allowing and encouraging the importation of medications from other countries without the appropriate regulatory safeguards is a serious threat to our established and traditional regulatory foundation and to the health and safety of our most vulnerable population.

The topic of prescription drug distribution via the Internet is broad and complex. To effectively analyze the related public policy issues that exist, this broad context must be

dissected into its major components. Those who sell drugs over the Internet fall into one of three categories. They are either pharmacists dispensing drugs through a legitimate licensed pharmacy regulated by the state boards of pharmacy, they are legitimate licensed prescribing practitioners regulated by their state professional regulatory agencies (board of medical examiners, board of dentistry, etc.), or they are neither authorized dispensers nor authorized prescribers. Individuals in these categories are operating fraudulent rogue web sites deceiving consumers into believing they have some authority to prescribe, dispense or distribute prescription drugs. These are the sites advertising prescription drugs without a prescription. These are the criminal elements that evade the resources and authority of the states and they exist both inside and outside the U.S. This is where the resources and authority of the federal government and Congress is sorely needed. The state boards of pharmacy and medicine can handle pharmacists and pharmacies and doctors in the U.S. However, the states are helpless in the face of the invisibility, anonymity and covert mobility of rogue sites on the Internet.

The following list describes the concerns that the Board believes must be addressed by any federal legislation being considered.

1. Canadian pharmacists are prohibited by Canadian law from filling prescriptions written by U.S. physicians. To circumvent this law, Canadian pharmacists employ Canadian physicians to re-write prescriptions on their Canadian prescription forms, which means the prescription written by the U.S. physician is never filled. It may be simply filed away and stored in Canada, or it may destroyed by the local prescription broker in a effort to "cover their tracks" while a facsimile of the original prescription is transmitted to Canada. In either case, the Canadian physician takes no responsibility for the therapy or therapeutic outcome for the U.S. patient, and there is a risk that the original prescription written in the U.S. may have been written by someone who is not a licensed practitioner authorized to prescribe. Any plan that allows importation through Canadian pharmacists will continue to encourage and promote this "slight of hand" manipulation of the prescription, which violates legal, professional and ethical standards of both the U.S. and Canada. And, under current laws, the state Boards of Pharmacy cannot intervene if an error, injury, adverse outcome or death occurs when the drugs have been imported from another country.

2. The Board believes that the problem is not that drugs in Canada are "bad" or "inferior". Canadian people are healthy and are not falling dead because their drugs are bad. The Board's concern is related to the mechanisms and processes of retail drug distribution by Canadian pharmacies. If we allow importation of drugs from Canada, we must guarantee that the drugs received by U.S. citizens are the same as the drugs received by Canadian citizens. Unfortunately, ample evidence now exists to show that many drugs are passing through Canadian pharmacies from other countries, unregulated by Canadian or U.S. authorities, to unsuspecting U.S. citizens. The unregulated distribution of drugs into the U.S. creates a health risk to citizens by creating opportunities for the unscrupulous introduction of outdated, contaminated, or counterfeit drugs. It also creates an avenue for the introduction of drugs that have been illegally or improperly manufactured in another country. These tainted prescription medications could be easily dispensed

by unregulated rogue web sites or by "passing through" pharmacies in other countries such as Canada, Germany or Great Britain from their unidentified country of origin. Closed distribution channels that eliminate the risk of and the opportunities for the unscrupulous introduction of counterfeit or inferior drug products must be established and enforced. No matter where the safe and effective drugs originate, the state Boards of Pharmacy must ensure that a distribution system remains in place to guarantee that the drug product prescribed for and requested by the patient is exactly what the patient receives.

3. If importation of drugs from Canada is to be allowed under some type of regulated mechanism, it should be between the Canadian pharmaceutical wholesaler and the state licensed pharmacy in the U.S. This eliminates the prescription "slight of hand" manipulation by the Canadian pharmacist and physician that will lead to errors, and it puts the U.S. consumer back in touch with their own local pharmacist. It may be possible for drugs to be imported from a known safe foreign source through closed regulated wholesale distribution channels. Involvement with a very small number of Canadian wholesalers would provide a much more manageable safety risk and regulatory work load than a relatively large number of Canadian pharmacies and pharmacists. Additionally, The Board believes it is very important that even if a safe source of drugs from another country is available, the professional practice of pharmacists for U.S. citizens must remain subject to regulation by the U.S. states in which the pharmacists are licensed. The professional practice of pharmacists cannot be imported from a foreign country

4. If drug importation at the wholesale level is to be allowed, the foreign wholesale drug outlet must be willing to be licensed by the state or states into which it is sending drugs and to have documented business relationships with any pharmacy in the states with which it does business. In addition, it must be willing to submit to the regulatory jurisdiction of the state as a condition of licensure. The U.S. pharmacies and pharmacists are already licensed under their state's jurisdiction.

5. The Board of Pharmacy understands the hardships placed on many Oregonians and citizens across the country because of high drug prices. The Board also understands the risks associated with unregulated drug importation. The Board is working with the National Association of Boards of Pharmacy, the Canadian National Association of Pharmacy Regulatory Authorities, the FDA, Health Canada, the Oregon State Pharmacists Association, consumer groups, the Oregon Attorney General's office and Governor Kulongoski, studying ways to effectively address safety concerns and providing information to health professionals, legislators and consumers. The Board is also interested in working with state and federal legislators to identify real and lasting solutions to address Oregon and U.S. citizens' access to safe, affordable and effective health care.

6. Oregon Governor Ted Kulongoski has proposed a pilot project that is currently awaiting approval from the Secretary of Heath and Human Services. The "Pioneer Prescription Drug Project" announced by Governor Kulongoski in August of 2004 will allow prescription drug importation by Oregon pharmacists from Canada in a

controlled manner, regulated and monitored by the Oregon Board of Pharmacy. It is designed to improve Oregonian citizens' access to safe and affordable prescription drugs through Oregon pharmacies by providing appropriate regulatory guidance to pharmacists and pharmaceutical wholesalers. A description of the provisions of Governor Kulongoski's plan are included as an addendum to this testimony.

7. Even though the Internet provides vast opportunities for convenient access to a variety of legitimate products and services that may improve the quality of life of consumers, the Board is very concerned about drugs purchased through the Internet. Unsuspecting U.S. citizens are currently putting themselves at risk by purchasing prescription drugs via Internet sites which may appear to be legitimate pharmacies, but, in fact, may actually be unregulated rogue web sites without a licensed physician, pharmacy or pharmacist and may not be located in the U.S. If the U.S. Congress considers regulating pharmacy dispensing via the Internet, the Board urges that the Verified Internet Pharmacy Practice Site (VIPPS) model as currently administered by the National Association of Boards of Pharmacy (NABP) be adopted as the basis for regulation. The criteria for VIPPS certification provide assurances that the entity involved in dispensing is doing so in compliance with all applicable laws and regulations. In this way, the safety of U.S. consumers can be protected and the compliance with prescription dispensing regulations can be appropriately monitored.

   The Board believes that the intrastate and interstate licensing and regulation of pharmacy practice and drug distribution legitimately belongs at the state level as it currently exists. The state Boards of Pharmacy, through their association with the NABP, have developed cooperative relationships with regard to professional licensing and investigations. However, the international distribution of drugs via the Internet far exceeds the resources available to the state agencies and the authority of states to enforce regulatory compliance by entities outside the country.

The Oregon Board of Pharmacy is the sole agency entrusted by the Oregon legislature with the responsibility and authority to regulate the practice of pharmacy and the quality and distribution of drugs in the state in the interest of the public health, safety and welfare. Because of the risks associated with acquiring drugs from foreign countries or via the Internet, consumers are urged to talk with their pharmacist or physician to ensure the medications they are receiving are safe, effective, affordable and appropriate for their medical condition. Often, less expensive alternatives are available through their doctor and local pharmacy.

On behalf of the Oregon Board of Pharmacy, I appreciate the opportunity to address the Committee and I thank you for considering these concerns as they relate to foreign drug importation and Internet drug distribution legislation.

The CHAIRMAN. Senator Kohl, would you like to introduce your constituent?

Senator KOHL. Thank you, Mr. Chairman. I am pleased to introduce today Mary Jorgensen, who is here from Madison, WI.

For the past 16 years, Mary has worked for the Coalition of Wisconsin Aging Groups, a nonpartisan grassroots organization serving Wisconsin's senior citizens. She has a long history of working with seniors to improve their quality of life, most recently as Coordinator of the Coalition's Prescription Drug Information Center.

So Mary, we welcome you here today and we look forward to your testimony.

STATEMENT OF MARY JORGENSEN, PRESCRIPTION DRUG INFORMATION COORDINATOR, COALITION OF WISCONSIN AGING GROUPS, MADISON, WI

Ms. JORGENSEN. Thank you, Senator. Good morning. My name is Mary Jorgensen and I am the Coordinator of the Prescription Drug Information Center of the Coalition of Wisconsin Aging Groups, as Senator Kohl has stated.

As early as 1998, CWAG's members have been concerned about the high cost of prescription drugs in the United States. As an elderly advocacy organization, we began to look for affordable options for seniors other than ones available in Wisconsin. We also wanted to be able to counsel folks on the various cost-saving options available to seniors in Wisconsin.

Several of our 600 member groups were able to organize bus trips to Canada to purchase their drugs, where they saved substantially. This led to collaboration with our counterparts in other States to pursue additional options for seniors to save on their costs of prescription drugs.

After actual visits to Canada by CWAG staff and our counterparts, the decision was made to enter into an agreement with CanadaRX out of Ontario, Canada, where we would be able to assist seniors in purchasing their drugs. Our decision to work with CanadaRX was predicated, No. 1, on cost, since this is the main concern of our members. Our considerations were that CanadaRX has been in existence for over five years providing drug reimportation to the United States with a good reputation, and they are a licensed Canadian pharmacy.

In August 2002, CWAG began its Prescription Drug Information Center, where seniors could call for assistance. This provided an opportunity for seniors who have high prescription drug costs and were afraid to check into purchasing drugs from Canada on their own. CWAG provides all the tools necessary to purchase drugs from a reputable Canadian pharmacy and save on their prescription drug costs. Within the past year, we have added another licensed Canadian pharmacy, the Canadian Drug Service, to our list of options.

Many of our inquiries are from low-income seniors who do not qualify for other programs. Some have told me they could not continue to eat and buy their prescription drugs. Others told me they take their medications only every other day so their supplies last longer. This is a travesty.

We believe that unaffordable drugs are neither safe nor effective. People are being forced to choose between drugs and nutrition. Through prescription drug reimportation, they are able to afford both. Many of the seniors I speak with have cardiovascular disease, have suffered stroke or heart attack, or they have diabetes that requires several expensive drugs they simply cannot afford any longer from their local pharmacy.

Safety seems to be the No. 1 concern of the FDA regarding reimportation. These reimported drugs are shipped in the manufacturer's sealed packaging. Drugs sold in our U.S. pharmacies are being manually counted out by pharmacy technicians. The chance of the wrong drugs being dispensed is much greater than if the drugs were shipped in their original packaging. Purchasing drugs in the United States does not make it any safer than purchasing drugs from another country where the drugs are carefully manufactured and regulated.

As a grassroots organization of seniors, CWAG is more concerned about affordability than reimportation. CWAG continues to believe that unaffordable drugs are neither safe nor effective. We realize that reimportation is not for everyone. Not all drugs are available through reimportation, and some drugs are not cheaper, either.

The main purpose of my being here today is to support the legalization of prescription drug reimportation so that people have a choice to obtain cheaper drugs through this process if this is the best way of saving prescription drug costs on an individual basis.

With the implementation of the Medicare Modernization Act in 2006, seniors will be experiencing huge cost increases on their prescription drugs due to the doughnut hole in the prescription drug benefits. Why are seniors being asked to participate in such a confusing program when life should become simpler in their old age?

A simple solution, CWAG believes, would be for the Federal Government to be able to negotiate prices with the drug companies just as they do in Canada and other countries. Wisconsin is experiencing great success in reducing prescription drug costs for Medicaid enrollees and State employees. If States can successfully negotiate prices with drug companies, it seems that the Federal Government would have more clout in negotiating prices. If drugs were affordable here, we wouldn't need to go elsewhere.

In summary, CWAG will continue to advocate for Wisconsin's seniors. We again want to emphasize we do not believe drug reimportation is for everyone, but we will continue to fight for legislation to ensure safe reimportation of prescription drugs as an option.

Thank you for the privilege of being able to speak to you today on behalf of Wisconsin's seniors.

The CHAIRMAN. Thank you very much, Mary. We appreciate your traveling here to share your story. We wish you and all the people in your organization very well.

Ms. JORGENSEN. Thank you.

[The prepared statement of Ms. Jorgensen follows:]

4-77

TESTIMONY

OF

MARY JORGENSEN

Before

THE SENATE SPECIAL AGING COMMITTEE

INTERNET PHARMACY & DRUG REIMPORTATION:

Exploring Risks & Benefits

January 26, 2005

Good Morning. My name is Mary Jorgensen and I am representing the Coalition of Wisconsin Aging Groups located in Madison, Wisconsin. CWAG (Coalition of Wisconsin Aging Groups) is a grassroots, nonpartisan elderly advocacy organization whose mission for the past 28 years has been to work on behalf of frail and elderly who are unable to speak for themselves on issues affecting their quality of life in Wisconsin.

My current position with the Coalition of Wisconsin Aging Groups (I'm in my 16th year of employment with CWAG) is the Prescription Drug Information Center Coordinator. For the past 2 ½ years the Coalition of Wisconsin Aging Groups has provided a clearinghouse for our 600 member groups and 12,000+ individual members of our organization.

BACKGROUND OF CWAG'S PRESCRIPTION DRUG INFORMATION CENTER

As far back as 1998, CWAG's members have been concerned about the high cost of prescription drugs in the United States. As an elderly advocacy organization we began to look for affordable options for seniors other than the ones available in Wisconsin. We also wanted to be able to counsel folks on the various cost-saving

options available to seniors in Wisconsin. These choices include Wisconsin's SeniorCare program (CWAG was very instrumental in getting this legislation passed into law). This state program provides low-income seniors the opportunity to purchase their drugs at $5/prescription for generic drugs and $15/prescription for brand name drugs. Another option includes the special programs offered by various pharmaceutical companies and then, of course, the purchase of drugs from Canada. Because of our geographic location several of our 600 member groups were able to organize bus trips to Canada to purchase their drugs, where they saved substantial amounts of money. This led to discussion and collaboration with our counterparts in Minnesota, Indiana and Pennsylvania to pursue additional options for seniors to save money on their ever-increasing costs of prescription drugs. After actual visits to Canada by CWAG staff and our counterparts, the decision was made to enter into an agreement with CanadaRX, Ontario, Canada where we would be able to assist seniors (or any of our members for that matter) in purchasing their drugs. Our decision to work with CanadaRX was precipitated on several things. Number one was cost since this is the main concern of our members. Another consideration was the fact that CanadaRX had been in existence for over five years providing drug reimportation to the United States with a good reputation. The other consideration was that they are a licensed Canadian pharmacy.

AN OPTION THAT WORKS

In August 2002 CWAG began to offer an additional membership benefit of the Prescription Drug Information Center where seniors could access an internet site to do cost comparisons on their own or call CWAG for assistance. This provided a wonderful opportunity, especially for seniors, who have high prescription drug costs, were afraid to check into purchasing drugs from Canada or didn't have access to computers. CWAG provided all the tools necessary, including price quotations, to enable consumers to purchase their drugs from a reputable Canadian pharmacy and save as much as 60% of their drugs costs.

Within the past year we have added another vendor, Canada Drug Service, to our drug purchasing options because several of our members were unable to use the

services of CanadaRX due to their ordering process that involved the physician's signature on the order form as well as on the prescriptions. With Canada Drug Service, the process is much simpler and requires the doctor's signature only on the prescription. Canada Drug Service is also a licensed Canadian pharmacy. They are not an internet accessible provider—they have a presence in Wisconsin where consumers have a one-on-one contact.

Many of our inquiries are from low-income seniors who do not qualify for other programs—many of whom told me they could not continue to eat and buy their prescription drugs and still afford to live! Others have told me they take their medications only every other day so their monthly supplies last longer. This is a travesty! We believe that unaffordable drugs are neither safe nor effective. People are being forced to choose between drugs and nutrition—through prescription drug reimportation they are able to afford both.

Many of the seniors I speak with fall into a few typical scenarios—they have cardio-vascular disease, have suffered a heart attack or stroke, diabetes, etc. that require several expensive drugs they simply cannot afford any longer from their local pharmacy.

An example of the kind of savings seniors experience is with a couple living in southern Wisconsin. Bill's wife, Mary Lou, has suffered severely with asthma her entire life, along with other health problems. Mary Lou's medications cost approximately $4,900 each year. Bill does extensive price comparisons and has found that using Canadian pharmacies, he has been able to save approximately 35% in prescription drug costs each year. The Prescription Drug Information Center has received approximately 3,900inquiries from seniors within the past 2 ½ years of it's existence. Over 1,200 of our members have saved significant dollars on their prescription costs by purchasing their drugs from Canada and a few other countries such as New Zealand.

Safety seems to be the number one concern of the FDA regarding reimportation. These drugs are shipped in the manufacturer's sealed packaging (usually a three-month supply). The drugs sold in our U.S. pharmacies are being manually counted out by pharmacy technicians. The chance of the wrong drug being

dispensed is much greater than if the drug was shipped in its original packaging. As a matter of fact, I have an 81 year old friend who takes about 9 different pills each day. Within the past three years she has had two separate instances where the wrong drug was dispensed. Thankfully she was of sound mind and noticed the difference in color and shape of the pills and called this huge, nationally known pharmacy before ingesting the wrong drug that could have killed her (as she later discovered). Purchasing drugs in the United States does not make it any safer than purchasing drugs from another county where the drugs are carefully manufactured and regulated.

As a grassroots organization of seniors, CWAG is more concerned about affordability than the reimportation issue. CWAG continues to believe that unaffordable drugs are neither safe nor effective. It's important to mention that we realize that reimportation is not for everyone. Not all drugs are available through reimportation—insulin as an example. Some drugs are not necessarily cheaper either. *THE MAIN PURPOSE OF MY BEING HERE TODAY IS TO SUPPORT THE LEGALIZATION OF PRESCRIPTION DRUG REIMPORTATION SO THAT PEOPLE HAVE A CHOICE TO OBTAIN THEIR DRUGS THROUGH THIS PROCESS IF THIS IS THE BEST WAY OF SAVING PRESCRIPTION COSTS ON AN INDIVIDUAL BASIS.*

IMPACT OF THE MEDICARE MODERNIZATION ACT—WHAT ELSE CAN BE DONE?

With the implementation of the Medicare Modernization Act (without going into great detail), seniors will experience huge cost increases on their prescription drugs due in large part to the "donut hole" in prescription drug benefits. Why are seniors being asked to participate in such a confusing, unclear program when life should become simpler in their old age. A simple solution CWAG believes would be for the federal government to be able to negotiate prices with the drug companies just as they do in Canada and New Zealand for instance. The state of Wisconsin is experiencing great success in reducing Rx drug costs for Medicaid enrollees and state employees, and will soon make these savings available to individual Wisconsin citizens. If states can successfully negotiate prices with drug companies it seems that the federal government would have exponentially more clout in negotiating prices for

Medicare recipients, not to mention reducing the cost of the Medicare Part D Rx drug benefit. If drugs were affordable, we wouldn't need to go elsewhere.

IN SUMMARY, the Coalition of Wisconsin Aging Groups will continue to advocate in support of Wisconsin's senior population. We again want to emphasize we do not believe drug reimportation is for everyone, but for those seniors (and those of all ages, for that matter), we will continue to fight for legislation to assure that safe reimportation of prescription drugs as an OPTION for those who choose to use it in order to save money on their prescription drugs. Thank you for the privilege of being able to speak to you on behalf of Wisconsin seniors.

The CHAIRMAN. Roger Pilon, thank you, from the CATO Institute. I am informed there is a vote that has just started, but I think we have time to complete your testimony first.

STATEMENT OF ROGER PILON, VICE PRESIDENT FOR LEGAL AFFAIRS, CATO INSTITUTE, WASHINGTON, DC

Mr. PILON. All right. Then I will try to hurry right through it, Mr. Chairman.

The CHAIRMAN. Thank you.

Mr. PILON. Let me thank you and Senator Kohl for your invitation to be here this morning. I am going to summarize the written testimony I provided the committee, which itself is a summary of a much larger study that I made available to the committee, which is available at the CATO Institute website.

Let me begin by making very clear what I am here to urge and what I am not here to urge. I am not urging the committee and the Senate generally to enact a drug reimportation program or to set one up. I think that reimportation is the wrong answer to the problem that is before us. Lifting the ban on reimportation, however, is the right answer because it will allow market principles to surface, and they alone can sort out the competing interests in this matter.

Indeed, let me say that I was delighted to hear on the minority side so much talk of market principles. I only wish that the Bush administration, which speaks often of market principles, would adhere to them more often. But I digress.

The reimportation debate is before us, of course, as we have heard, because of the high cost of drugs in this country, and more particularly because of the disparity, the international disparity, between prices for drugs. So we want to know, why are there such high prices and why is there such an international price disparity?

The reason drugs cost so much to begin with, of course, is because it takes, as we have heard, some $800 million, on average, and 12 to 15 years before the FDA efficacy and safety standards are met; and, that means of course, that a drug company is in a large hole right off the bat. They have to recover those costs before they can make their first dime, and that means that they are going to have to charge whatever the market will bear to do that.

That doesn't answer, however, why there is such a price disparity internationally. For that, you have to look at a much more complex picture. When a drug company looks out at the world, it sees essentially one free market, in America, and here it charges whatever the market will bear. When it looks out at the rest of the world, however, it sees socialized medical systems abroad and price controls. Essentially, the companies tell us they have to take what the foreign governments offer them. They can afford to do that, however, only because they can fall back on the relatively free American market, which is about half the world market, to make up the amount that they need in order to cover their R&D costs and the profit that is necessary to attract capital for future R&D—which, of course, we all want to see done.

There is another explanation, however, that puts the companies more in the driver's seat, and it draws from economic theory. It is that the companies see different levels of demand in different coun-

tries, and what they try to do is segment markets and price differentially. If you charge too high, you are going to attract too few buyers. If you charge too low, you will exclude buyers who are willing to pay more. So they are trying to find the optimal price in each market.

The only problem with that is when you segment markets and discriminate with prices, you have to guard against parallel trading—that is to say, buyers in low-price markets reselling to high-price markets—because if that is the case, what you will have is all the drugs flowing to the low-price markets and not to the high-price markets and it will undercut the profit margin that you have to have to sustain your business.

There are two legitimate ways to go about that—to prevent the kind of parallel trading that I have just spoken of. The first is through no resale contracts; and the second, if those should fail, is through supply limits.

What companies did in 1987 however, was take the illegitimate route and imposed a statutory ban. They sought, in effect, a public law solution to a private law problem, and the problem with that is this. First of all, if you don't have no resale contracts in place, it is preventing willing sellers from getting together with willing buyers. If you do have no resale contracts in place, you are going after the wrong person, the American buyer. The person who is breaching the contract is the person that the company should go after.

So if the company wants to try to have market segmentation and price discrimination, the way to do it is to go to these countries and say, look, we will give you a lower price, but you police your exports. It is not up to the American government to police imports.

Now, it is my view that if that strategy were to be followed, you would probably have a good test as to whether it can be sustained, and my sense is it cannot. That is to say, the greater the disparity between the prices, the greater the incentive to breach the walls separating the markets, and we are seeing this already when we have got a statutory ban. We have already heard testimony this morning about how people are simply ignoring the law. Indeed, State officials are ignoring the law.

So it strikes me that even with no resale contracts and with supply limits, eventually, you are going to have to have the third remedy, namely companies are going to have to readjust their prices, raising them sufficiently abroad and/or lowering them here, to stall reimportation; and that means, in effect, that you will not have reimportation. That is why I have urged in my testimony that you really don't need these complex kinds of bills that have been introduced that are all aimed at safety because reimportation is not the answer to this issue. If you allow market principles to surface, you simply won't have reimportation. You will have the threat of reimportation—and that will do the job.

It seems to me that what you do have to do, then, is look at these bills, like the Dorgan-Snowe bill that was discussed earlier this morning. Look at the "anti-gaming" provisions that have been put in that bill. Those are absolute killers. That is not a market approach. Those are anathema to markets. They would prohibit companies from raising prices abroad or limiting supplies abroad. In

other words, they are tantamount to importing foreign price controls, exactly what the drug companies fear, and rightly so, because they would mark the end of the money for research for the future miracle drugs that we all want to see produced. So it seems to me that if you are going that route, you need to seriously think about it.

Let me say finally that I have listened to you beating up on the administration here this morning. With all due respect, the problem is not in the administration. The executive branch doesn't write the laws. The legislative branch writes the laws. The problem with this ban is right here in Congress.

So I submit that the answer is very simple. Lift this ban and let the market work.

The CHAIRMAN. Thank you very much, Roger. That was very insightful.

[The prepared statement of Mr. Pilon follows:]

Statement of

Roger Pilon, Ph.D., J.D
Vice President for Legal Affairs
B. Kenneth Simon Chair in Constitutional Studies
Director, Center for Constitutional Studies
Cato Institute

"Legalizing Prescription Drug Importation"

before the

Special Committee on Aging
United States Senate

January 26, 2005

Mr. Chairman, distinguished members of the committee:

My name is Roger Pilon. I am vice president for legal affairs at the Cato Institute and director of Cato's Center for Constitutional Studies. I want to thank the committee for inviting me to appear today to discuss legalizing prescription drug importation. In this statement I will simply summarize points I made in greater detail in my August 4 *Cato Policy Analysis No. 521*, "Drug Reimportation: The Free Market Solution," a copy of which is attached (available at http://www.cato.org/pubs/pas/pa521.pdf). Attached also is a copy of my October 11 *Wall Street Journal* op-ed, "The Reimportation Blues" (available at http://www.cato.org/cgi-bin/scripts/printtech.cgi/research/articles/pilon-041011.html) and a biographical sketch.

Let me begin by stating clearly that *I am not here to urge Congress to pursue a policy of drug reimportation*, as that idea has come to be called. However attractive such a course might initially seem, reimportation is not the answer to the problem, if it is a problem, of high prescription drug prices in America. Rather, *I am here to argue mainly for lifting the current statutory ban on reimportation*. That will better enable market principles and practices to surface, which alone can sort out the competing claims that arise in the drug reimportation debate. I'll now develop those points a bit more fully and conclude with a few additional points that do need Congress's attention.

The reimportation debate is before us, of course, because in recent years, owing in part to the rise of the Internet, Americans in increasing numbers have discovered that the patented prescription drugs they're using cost considerably less abroad. But they've also learned that American law, except under limited circumstances, prohibits them from buying those lower priced drugs. Thus, they're pressing Congress to lift the ban in the hope of lowering their medical bills. But in the meantime, they and many state and local officials are simply ignoring the ban and purchasing drugs abroad.

Why then do drugs cost so much? And why is there such a disparity between domestic and foreign prices? The answer to the first question points to the regulatory regime we've established in this country to ensure drug safety and efficacy. Rather than rely on common law principles to allocate the risks of unsafe or inefficacious drugs, early in the last century we established the Food and Drug Administration (FDA) and asked it to regulate the invention, manufacture, and distribution of drugs by private profit-making companies. Today, to win FDA approval for a new drug, a company must invest on average between 12 and 15 years and $800 million in research and development (R&D) before the drug reaches the market. In few industries is the ratio of R&D costs to those of manufacturing and marketing greater. The first pill is enormously expensive; the second costs almost nothing to produce.

In a moment I'll show how that first-pill/second-pill cost disparity is tied to the international price disparity, but first I want to note that the costly FDA approval process reflects the extremely risk-averse posture that we've taken. That posture is not cost-free, however, for in guarding so heavily against the risk of an unsafe or inefficacious drug, we've discounted the risk incurred by a drug's being unavailable, because not yet approved, or too costly. Suffice it to say that a more flexible FDA approval process, one that allowed for greater individual assumption of risk, would better balance those competing risks.

Given those extraordinary up-front costs, however, companies must charge prices sufficient not only to recover their investment but also to ensure future investment in drug R&D, or they'll not be long in business. And they've got only a limited time to do that because the 20-year clock on patents starts ticking from the time the company first applies for FDA approval, which means that drug patents run about half as long as other patents. Once the patent ends, others can produce the drug as a generic.

We come then to the second question: Why such a disparity between domestic and foreign drug prices? Some question whether there is a disparity, so let me grant first that for a number of reasons—including, most recently, the falling value of the dollar—international price comparisons are not easy to make. Nevertheless, domestic prices tend generally to be well above those abroad. In 2002, for example, patented drug prices here were 67 percent higher on average than in Canada, according to that country's Patented Medicine Prices Review Board. For the average American, however, what matters is the disparity in the prices of the drugs *he* uses, and that's what's driving the debate. So what explains the disparity?

There are two main reasons. First, when drug companies look at the world they see essentially one free market—America. Here they can set prices at levels that aim at maximizing profits. In the rest of the world, companies tell us, socialized medical systems set prices: "monopsony" buyers make take-it-or-leave-it offers. Because a company's marginal cost for the second pill is so low, as noted earlier, it can accept those offers and still come out ahead. But it can do so only because it has America—half the world market—to fall back on. In effect, the rest of the world rides free—or at least at

well below cost—while American citizens pick up the tab for drug R&D. And that, too, is driving this debate.

Given that scenario, it's no surprise that companies oppose lifting the importation ban. For if we imported drugs at those controlled prices we'd undercut the profits they make in the large American market, thereby rendering them unable to attract the capital they need for future R&D. And that would be bad for everyone, Americans and foreigners alike. In effect, as the companies rightly say, we'd be importing foreign price controls. If that's the case, why not simply impose the price controls ourselves and forego the added costs of reimportation? We don't do that, of course, because in this country, at least, we understand the folly of price controls—even as the rest of the world enjoys them at our leave.

But the scenario the companies describe, which renders them and us hapless victims of foreign price controls, is not the whole story. And so we come to the second, equally important reason for international price disparities—an explanation that puts companies more in the driver's seat. Recognizing different levels of demand in different countries, companies try to maximize profits by segmenting markets and pricing differentially. Selling too high in low demand markets excludes too many potential buyers, while selling too low in high demand markets excludes too many buyers willing to pay more. Market segmentation is a perfectly legitimate marketing strategy, but it invites parallel trading—buyers in low price markets reselling to high price markets, outside the control of the companies. When that happens, the advantages of market segmentation are lost. In fact, that's what drug reimportation would amount to, which is another reason companies oppose it.

Consistent with market principles, companies that segment markets and price differentially have two ways to try to frustrate parallel trading—no-resale contracts and supply limits. A statutory reimportation ban of the kind now in place, however, is inconsistent with market principles because (a), absent no-resale contracts, such a ban interferes with free trade, and (b), with no-resale contracts in place, a ban restricts the wrong party—the American buyer, who is no party to the contract. There are proper and improper ways to enforce market segmentation. We've chosen the improper way.

Actions to enforce no-resale contracts should be brought by the companies against breaching parties. If enforcement actions should fail, however, the proper response is for companies to limit supplies, as they're doing now in the case of Canada. Companies should never have run to Congress, as they did in 1987, seeking a ban on importing drugs; and Congress should never have granted such a request, which amounts to a passive subsidy to the companies. If they want to sell drugs to foreign governments at below "true cost," they need to say to those governments, "We'll sell to you at below cost, but you'll have to police your exports. It's not up to the American government to police imports." That gets the incentives right, putting the enforcement burden where it belongs, on the party receiving the benefit of the bargain. Today, however, not only do Americans pay the bulk of drug R&D costs; they also pay the costs of enforcing the ban that enables the rest of the world to escape those costs.

Thus, if the reimportation ban were lifted, and market principles and practices were to take its place, it would not follow necessarily that domestic drug prices would drop or that the free-rider problem would abate. In a free market, sellers and buyers are free to strike whatever bargains they wish. Americans might thus continue to face high prices if foreigners were unwilling to resell their limited supplies to them. But as price differentials increase, incentives on both sides to breach the market barriers only grow, as we are seeing today, even with a statutory ban in place. Thus, in a world of large differentials, multiple vendors, and ready information, it's not likely that no-resale contracts and supply limits would long stanch the cross-border flow of drugs. Companies in that case would have no choice but to adjust prices, raising them abroad and/or lowering them here sufficiently to discourage parallel trading.

Yet insofar as the reimportation ban is effective in restricting cross-border trade, companies to that extent are disinclined to take such measures—and disinclined, in particular, to do the hard bargaining that would "force" foreign governments to take on a greater share of the true costs of drug R&D. Today, we have no way of knowing whether foreign governments would be able or willing to pay more for drugs because companies, able to fall back on the American free market, have limited incentive to press the issue. The reimportation ban, in short, skews the incentives against American citizens, forcing them in effect and in fact to subsidize socialized medical systems abroad. It is a wholly un-American arrangement that should be ended immediately.

Congress does not need to exercise itself, therefore, with drafting extraordinarily complex measures of the kind we've seen, all to try to ensure that reimported drugs will be safe. *Just lifting the ban will do.* Companies already have more than enough market and legal incentives to ensure that their drugs, domestic or reimported, are safe. More to the point, the mere lifting of the ban should suffice to address the safety issue, by default, because with the ban lifted, companies will resort to no-resale contracts or supply limits or both; and if those should fail they will resort to price adjustments, all of which means that there will be little or no reimportation—which makes no sense to begin with—and *that will render the safety issue moot.* Indeed, it is the mere *threat* of reimportation that will bring equilibrium about. And so, as with so much else in life, this issue turns out to be simpler than at first it seems—once we get the principles right.

Nevertheless, there are related issues that Congress should address, which I discuss more fully in my August 4 study. Let me simply outline a few here.

Most important, in whatever measures Congress enacts, "anti-gaming" provisions of the kind that are found in the Dorgan-Snowe bill (S. 2328) of the last session of Congress must be avoided. Designed generally to prohibit companies from raising prices or limiting supplies abroad, such measures are likely unconstitutional; and if not, they truly would amount to importing foreign price controls. If that's what we want, then apply controls directly, as noted earlier. But of course that would mark the end of the market incentives now in place that have given us the miracle drugs that have so changed modern medicine—and no one wants that.

The Judd Gregg bill (S. 2493) does not contain such provisions. Its problem, rather, is in trying to micromanage reimportation, as if it would happen, by implementing a program for Canada to start a year after enactment, and then waiting two more years before starting reimportation from Europe and a few other developed countries. Were that course to be followed, companies probably could "game" the tiny Canadian market (about five percent of the American market), which is too small in any event to satisfy American demand. With companies limiting supplies, Canadian wholesalers would have incentives to seek supplies from the rest of the world, which would open the door to substandard drugs produced under compulsory licensing in third-world countries (see below). For those and other reasons, the two-year "experiment" in limited reimportation would likely fail before the large European market kicked in, and we'd be back to reimposing the reimportation ban. No, the ban should be lifted all at once. Then let the market sort the issues out.

On another matter, the Dorgan-Snowe bill, to its credit, does seem to address the complex patent law issues that have arisen since the U.S. Court of Appeals for the Federal Circuit handed down its *Jazz Photo* decision in 2001 (*Jazz Photo Corp v. United States International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001)). This is a confused area of the law today, with experts on all sides unsure about what the law is. In a nutshell, when a patent owner sells a product, he is said to have exhausted control over subsequent sales (not over the invention). But patent law is country specific, so we have two rules: the international exhaustion rule says that a sale anywhere exhausts the owner's subsequent control of sales; the territorial exhaustion rule says that a sale abroad exhausts control only in that country, which means that the owner retains the right to control reselling to other countries. The effect of the *Jazz Photo* court's having upheld the territorial rule seems to be that drug companies can invoke *patent* law to block reimportation—*i.e.,* they can use arguably overextended property law to try to accomplish what should be accomplished through contract law. The Dorgan-Snowe bill addresses that issue by enacting, in effect, an international exhaustion rule.

But this issue is further complicated by recent treaties—in particular, the free-trade agreements that were signed and ratified last year with Australia, Singapore, and Morocco, all of which appear to have established the territorial exhaustion rule between the parties. Here too, however, the issue is unclear, the language dense; but it has all the marks of an effort to frustrate reimportation in anticipation of the direct ban's being lifted.

Finally, there is the larger patent issue that is said to arise when drug companies threaten to raise prices in a foreign country and are met with the counter-threat that, if they do, the country will invoke the compulsory licensing provisions of the WTO TRIPS Agreement and will license a local company to reverse engineer the drug, manufacturing it as a generic. Compulsory licensing amounts to stealing the patent, of course, and companies are rightly concerned about such threats, if they exist. Unfortunately, the language of the TRIPS Agreement allowing compulsory licensing is not as tight as it might be. But the 2001 Doha Declaration and the August 2003 follow-up agreement, together with surrounding documents, suggest that compulsory licensing is to be used

only by poor countries under limited conditions, not by developed countries in bargaining over prices. In fact, some 41 countries have agreed not to so use those provisions. Nevertheless, this is an area in which Congress and the executive branch need to be vigilant, because the integrity of the international patent system is essential to the continued health of the American pharmaceutical industry, which in turn is essential to the health of the nation.

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The Reimportation Blues

By Roger Pilon

It seems the issue of drug reimportation is finally ready for prime time. In Friday night's debate, John Kerry reaffirmed his support for drug reimportation while President Bush said he would consider supporting it if he could be certain it was "done in a safe way." A bill lifting the federal ban on reimporting prescription drugs passed the House last year, overwhelmingly. Three such bills now sit in the Senate. Several state and local officials, defying federal law, have begun their own reimportation programs.

If this is the direction of things, it's time to look seriously at the issue, because it's not as simple as many seem to think. Right now the issue is being staged as a morality play. Greedy drug companies are gouging seniors, only to sell drugs cheaply abroad. If they can make a profit there, at lower prices, they can do it here, critics say. Let's lift the ban and buy drugs at foreign prices. If it were that simple, the deed would have been done long ago. Yes, the federal ban should be lifted, but then the market should be allowed to work. If a bipartisan Senate bill succeeds, however, that second step won't happen.

* * *

International price comparisons are difficult to make. Still, Canada's review board recently reported that Americans pay on average 67% more than Canadians for patented drugs. The European differential is also substantial. To average Americans, however, what matters is the price of *their* drugs. They go online or they board buses to Canada and they're shocked by the difference. So they ask why.

Here's why, in a nutshell. Modern "miracle drugs" don't come cheaply. Given onerous FDA safety and efficacy standards, it takes on average 12 to 15 years and $800 million before a company can bring a new drug to market. Before the first dollar of profit comes back, those R&D costs have to be recovered, of course. But a company looks at the world and sees essentially one free market, America. Socialized medical systems abroad impose price controls. Seeing that, companies charge market prices here (half the world market) and take what they're offered abroad. Foreigners are classic "free riders" as Americans pay most of the R&D costs.

That part of the story portrays Americans and companies alike as victims of foreign price controls. There's another part, however: the economic rationale that puts companies in the driver's seat. When they look at the world, companies see different levels of demand. To maximize profits, therefore, they segment markets and price differentially. Nothing's wrong with that: airlines and theaters do it. Pricing too high excludes too many buyers. Pricing below what buyers are willing to pay yields too little profit.

> *Americans are subsidizing socialized medicine abroad.*

Probably both scenarios are in play, but on either, companies have to guard against "parallel markets"—drugs being *resold* by local vendors from low-price to high-price markets. If they don't, all their drugs will eventually go to the low-price markets, where companies don't recover true costs, only to be resold to high-price markets, thus undercutting the companies' profit-making venues.

Companies have two basic ways to preserve market segmentation: no-resale contracts, and supply limits. Both are consistent with free market principles. Back in 1987, however, drug companies took a short cut: they asked *Congress* to ban drug reimports. They won a statutory, public law solution to a private law problem, and therein lie difficulties.

In effect, third-party Americans were told they couldn't buy from willing foreign sellers. (In fact, Canadian provincial officials are actually *encouraging* local pharmacies to resell to Americans.) Thus, by opposing reimportation, the administration comes off as anti-free trade. Americans resent the price differences and the interference—especially those who understand the free-rider issue.

What's to be done, then? Clearly, the situation today is politically unsustainable, as events are proving. The ban should be lifted, therefore, not to encourage reimportation, which isn't likely to happen, but simply to allow market practices to surface. Today, with their high-profit American market protected, companies don't have to bargain hard abroad. The ban shields them, allowing them to claim they have to accept foreign price controls. Practically, Americans are subsidizing socialized medical systems abroad.

But with the ban lifted, and the threat of underpriced drugs flooding the American market, companies would be "forced" to adjust. They could still try to maximize profits by segmenting markets. But they'd have to guard against parallel markets the right way, through no-resale contracts or supply limits. They could offer a country lower prices, but the country would have to police its exports, since America would no longer be policing imports. That places the incentive where it belongs, on the country benefiting from the bargain. And if that failed, companies could limit supplies, as they're doing now with Canada.

In Europe, however, no-resale contracts are illegal—from a mistaken belief that they're anti-free trade. That's why there's a thriving parallel market there. If that's the way Europeans want it, companies will have no choice but to limit supplies or raise prices. That's how markets work. Companies should be free to segment markets. But if it doesn't work, international prices will move toward equality. And if that happens—as is likely, given enforcement difficulties—there'll be no reimportation, which moots the safety issue as well.

With the ban lifted, no one knows whether prices will rise abroad and fall here, or just rise abroad. That's for markets to decide. The last thing we want, however, is the bipartisan Dorgan-Snowe Senate bill, which would lift the ban and then prohibit companies from "gaming the system"—limiting supplies or raising prices abroad. In effect, the sponsors want to freeze the current situation, then import below-cost drugs from abroad—at those prices. The sponsors seem not to appreciate that the only reason a company can sell a drug for $20 in Germany is because it's sold for $100 in America. The bill would actually import foreign price controls, and that would be the end of future R&D and the miracle drugs it produces.

Opponents of lifting the ban say that if we "forced" market practices on the world, countries would balk at paying those prices and would steal American patents. But a close reading of the WTO Trips Agreement, protecting intellectual property, should allay those fears. The administration needs to watch the issue, however; and in treaty negotiations it should encourage a clear separation of commercial and charitable undertakings. In particular, the "compulsory licensing" arrangements designed to help poor countries with their drug needs should be scrapped in favor of a more market-oriented approach to this problem.

Drug reimportation is thus more complex than at first it seems, but as with so many other issues on the public's plate today, a healthy dose of market principles is the right prescription.

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Biographical Sketch

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Roger Pilon is the founder and director of the Cato Institute's Center for Constitutional Studies. Established in 1989 to encourage limited constitutional government at home and abroad, the center has become an important force in the national debate over constitutional interpretation and judicial philosophy. Pilon's writings have appeared in the *New York Times, Washington Post, Wall Street Journal, Los Angeles Times, Legal Times, National Law Journal, Harvard Journal of Law & Public Policy, Stanford Law & Policy Review,* and elsewhere. He has appeared on ABC's "Nightline," CBS's "60 Minutes II," National Public Radio, Fox News Channel, CNN, MSNBC, CNBC, and other media. He lectures and debates at universities and law schools across the country and testifies often before Congress. Prior to joining Cato Pilon held five senior posts in the Reagan administration, including at State and Justice. He has taught philosophy and law and was a national fellow at Stanford's Hoover Institution. At present he is an adjunct professor of government at Georgetown University through The Fund for American Studies. Pilon holds a B.A. from Columbia University, an M.A. and a Ph.D. from the University of Chicago, and a J.D. from the George Washington University School of Law. In 1989 the Bicentennial Commission presented him with the Benjamin Franklin Award for excellence in writing on the U.S. Constitution. In 2001 Columbia University's School of General Studies awarded him its Alumni Medal of Distinction.

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The CHAIRMAN. We appreciate your attendance, all of you. Out of respect for your time, rather than reconvene after a recess, I will leave the record open and any Senators wishing to ask you questions in writing may do so.

At this point, I would like to insert into the record a statement from Senator Russ Feingold.

[The prepared statement of Senator Feingold follows along with prepared statement of Senator Collins:]

PREPARED STATEMENT OF SENATOR RUSS FEINGOLD

I first want to take a moment to congratulate the new leadership of this Committee. Mr. Chairman, I look forward to working with you to address the many pressing issues facing our aging population.

I especially wish to acknowledge the new Ranking Member of this Committee, my fellow Senator from Wisconsin, Senator Kohl. The Committee will be well served by his leadership. He has long been a strong advocate for seniors in our state, and will continue to be a champion for seniors across the country in this new role.

I am pleased that Mary Jorgenson of the Coalition of Wisconsin Aging Groups is here before the Committee today to offer her insight into an issue of great importance to the people of Wisconsin. The Coalition of Wisconsin Aging Groups is the gold standard for advocacy—they have helped to put seniors' issues at the forefront of public debate. One of the many issues they have tirelessly worked to address is the skyrocketing cost of prescription drugs. The Coalition has fought to help seniors have access to affordable and safe prescription drugs from Canada, and I know that Ms. Jorgenson has a lot to say about this issue from her experiences working with the Coalition.

Mr. Chairman, I also want to thank you for making this issue a priority by addressing it during your first hearing as Chairman of the Committee. The skyrocketing costs of prescription drugs is one of the most important issues this Committee should examine this year. While I pleased that seniors will soon have some help with these costs through the new prescription drug benefit under Medicare, we must do more to make prescription drugs truly accessible for all seniors. While we need to ensure that prescription drugs purchased from other countries, especially over the internet, are safe and effective, we also need to also keep in mind that if it is neither safe nor effective to have seniors who cannot afford prescription drugs.

Each year, I travel to all 72 counties in Wisconsin and hold a listening session in each one. And for the past twelve years, the high cost of health care, and specifically the skyrocketing prices of prescription drugs, has been one of the top issues raised at these meetings by my constituents all across Wisconsin.

I am a strong supporter of the bipartisan bill introduced last Congress by Senators Dorgan and Snowe that will help Americans purchase prescription drugs at reduced prices, through the internet and through their local pharmacy. Without it, Americans are at the mercy of the pharmaceutical companies, which are raising the prices of the most commonly prescribed brand name drugs at twice the rate of inflation. It is our duty in the Senate to provide some relief. People in the United States pay substantially more for prescription drugs than people in any other industrialized country.

I have long supported efforts to create a competitive marketplace for prescription drugs. Drug manufacturers are free to move their factories to countries that have cheaper labor or greater tax incentives and to buy supplies from countries with the lowest costs, but Americans cannot purchase the drugs they need that are offered at lower prices in other countries. That doesn't make sense.

A growing number of American seniors, including a growing number of Wisconsinites, are obtaining their prescription drugs from Canada, whether they cross the border in person, order their prescriptions online, or go to one of the Canadian-company storefronts that have opened in this country.

Seniors are forced to go to Canada because the price of prescription drugs in this country is out of control. The Congressional Budget Office estimates that brand-name drugs cost, on average, 35 to 55 percent less in other industrialized countries than they do in this country.

Drug companies say that they need to charge high prices to recover the enormous research costs involved in bringing new medicines to market. Yet that argument overlooks the fact that Americans already fund much of the research and development of prescription drugs through taxpayer-funded research conducted at the National Institutes of Health and through tax breaks to the drug industry.

It is simply unfair that some Americans cannot afford the prescription drugs that their tax dollars help develop. It is far past time for Congress to allow Americans access to safe prescription drugs at the prices that the rest of the industrialized world enjoys.

PREPARED STATEMENT OF SENATOR SUSAN M. COLLINS

Mr. Chairman, I want to commend you for holding this important hearing to examine the risks and benefits associated with prescription drug importation and the purchase of prescription drug over the Internet.

One of the greatest challenges facing American consumers is the high cost of prescription drugs. Soaring prescription drug costs have placed a tremendous strain on family budgets. They have also imposed a heavy burden on employers—both public and private—who are struggling to provide affordable health insurance coverage to their workers. It is therefore no wonder that American consumers everywhere are looking across the border and into their computer screens in search of more affordable prescription drugs.

It is well-documented that the average price of prescription drugs is much lower in Canada and Western Europe than in the United States, with the price of some drugs in my home state of Maine being twice that of the same drugs that are available only a few miles away in a Canadian drug store.

It simply does not seem fair that American consumers are footing the bill for the remarkable, yet costly, advancements in pharmaceutical research and development, while our neighbors just across the border receive those same medications at substantially lower prices. That is why I have long supported legislation to allow American consumers to benefit from international price competition on prescription drugs by permitting FDA-approved medicines made in FDA-approved facilities to be re-imported into this county. But I am also concerned that we make certain that this is done safely and responsibly.

I am pleased that this morning's hearing will also focus on a slightly different but closely related issued—the safety challenges posed by the sale of prescription drugs over the Internet.

The growth of the Internet in recent years has created many new opportunities for consumers to shop on-line for health-related products, information and services. The Internet offers many advantages for on-line shoppers—convenience, competitive prices, privacy, and easy access to health and medical information. Moreover, through the Internet, individuals with disabilities, the elderly, and patients living in remote areas can easily obtain information, products and services that they previously acquired only with great difficulty. As a consequence, the sale of consumer products over the Internet has grown rapidly, including the sale of prescription drugs.

The number of on-line pharmacies has increased dramatically from the 190 identified by the Government Accountability Office (GAO) in October of 2000 to an estimated 1,400 sites in April of 2004. While online drugs sales by reputable pharmacies can have many advantages for patients, they also present new and unique challenges for regulators, law enforcement and policymakers. And rogue online pharmacies can be a prescription for disaster for unwary consumers.

Last June, I participated in a hearing held by the Senate Permanent Subcommittee on Investigations (PSI) which revealed disturbing evidence about the ease with which U.S. consumers can purchase dangerous and often addictive controlled substances from Internet pharmacy websites. I was particularly alarmed to learn that more than 90 percent of on-line sites do not require a prescription or validate that there is a legitimate patient-physician relationship.

I believe that we need legislation to protect consumers from these rogue internet pharmacies. This is one of the primary reasons that I have joined Chairman Smith in cosponsoring Senator Gregg's Safe IMPORT Act, which establishes federal licensing requirements and penalties for all Internet pharmacies that conduct or solicit business in the United States. The legislation also requires verification of a legitimate patient-prescriber relationship, and establishes verification procedures for all prescriptions.

Mr. Chairman, while I believe that we must do all that we can to make prescription drugs more affordable, we must also do all that we can to ensure patient safety. This hearing is an important part of that process, and I commend the Chairman for raising these important issues.

The CHAIRMAN. With that, we thank you again and we are adjourned.

[Whereupon, at 11:53 a.m., the committee was adjourned.]

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